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A Service Oriented Architecture to Implement Clinical Guidelines for Evidence-based Medical Practice.

By

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A Service Oriented Architecture to Implement Clinical Guidelines for Evidence-based Medical Practice

Summary

Health information technology (HIT) has been identified as the fundamental driver to streamline the healthcare delivery processes to improve care quality and reduce operational costs. Of the many facets of HIT is Clinical Decision Support (CDS) which provides the physician with patient-specific inferences, intelligently filtered and organized, at appropriate times. This research has been conducted to develop an agile solution to Clinical Decision Support at the point of care in a healthcare setting as a potential solution to the challenges of interoperability and the complexity of possible solutions. The capabilities of Business Process Management (BPM) and Workflow Management systems are leveraged to support a Service Oriented Architecture development approach for ensuring evidence based medical practice. The aim of this study is to present an architecture solution that is based on SOA principles and embeds clinical guidelines within a healthcare setting. Since the solution is designed to implement real life healthcare scenarios, it essentially supports evidence-based clinical guidelines that are liable to change over a period of time.

The thesis is divided into four parts. The first part consists of an Introduction to the study and a background to existing approaches for development and integration of Clinical Decision Support Systems. The second part focuses on the development of a Clinical Decision Support Framework based on Service Oriented Architecture. The CDS Framework is composed of standards based open source technologies including JBoss SwitchYard (enterprise service bus), rule-based CDS enabled by JBoss Drools, process modelling using Business Process Modelling and Notation. To ensure interoperability among various components, healthcare standards by HL7 and OMG are implemented. The third part provides implementation of this CDS Framework in healthcare scenarios. Two scenarios are concerned with the medical practice for diagnosis and early intervention (Chronic Obstructive Pulmonary Disease and Lung Cancer), one case study for Genetic data enablement of CDS systems (New born screening for Cystic Fibrosis) and the last case study is about using BPM techniques for managing healthcare organizational perspectives including human interaction with automated clinical workflows. The last part concludes the research with contributions in design and architecture of CDS systems.

This thesis has primarily adopted the Design Science Research Methodology for Information Systems. Additionally, Business Process Management Life Cycle, Agile Business Rules Development methodology and Pattern-Based Cycle for E-Workflow Design for individual case studies are used. Using evidence-based clinical guidelines published by UK's National Institute of Health and Care Excellence, the integration of latest research in clinical practice has been employed in the automated workflows. The case studies implemented using the CDS Framework are evaluated against implementation requirements, conformance to SOA principles and response time using load testing strategy.

For a healthcare organization to achieve its strategic goals in administrative and clinical practice, this research has provided a standards based integration solution in the field of clinical decision support. A SOA based CDS can serve as a potential solution to complexities in IT interventions as the core data and business logic functions are loosely coupled from the presentation. Additionally, the results of this this research can serve as an exemplar for other industrial domains requiring rapid response to evolving business processes.

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This thesis is dedicated to all the patients; with the hope that in future, evidence based clinical informatics will have a promising effect on their diagnosis and treatment.

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List of Acronyms

Acronyms

A&E	Accident and Emergency
API	Application Programming Interface
BPM	Business Process Management
BPMN	Business Process Modelling and Notation
CCD	Continuity of Care Document
CDS	Clinical Decision Support
CF	Cystic Fibrosis
CIG	Computer Interpretable Guidelines
COPD	Chronic Obstructive Pulmonary Disease
EBM	Evidence Based Medicine
eCHR	Electronic Clinical Health Record
ED	Emergency Department
EHR	Electronic Health Record
GT	Genetic Testing
HL7	Health Level 7
HIMSS:	Healthcare Information and Management Systems Society
HIPAA Act, 1996	Health Insurance Portability and Accountability Act, 1996
HIS	Health (or Hospital) Information System
NBS	Newborn Screening
PAS	Patient Administrative System
SCA	Service Component Architecture
SDLC	Software Development Life Cycle
SNOMED CT	SNOMED CT Systematized Nomenclature of Medicine - Clinical Terms
SOA	Service Oriented Architecture
vMR	Virtual Medical Record
WfMS	Workflow Management System
WGS	Whole Genome Sequence
WS	Web Services
XML	eXtensible Markup Language

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List of Publications

1. **Aziz, A.**, Rodriguez, S., & Chatwin, C. (2014). From Guidelines to Practice: Improving Clinical Care through Rule-Based Clinical Decision Support at the Point of Care. In Rules on the Web. From Theory to Applications (pp. 178-185). Springer International Publishing.
2. Rodriguez, S., **Aziz, A.**, & Chatwin, C. (2014). Enabling Healthcare IT Governance: Human Task Management Service for Administering Emergency Department's Resources for Efficient Patient Flow. Studies in health technology and informatics, 202, 87-90.
3. Rodriguez-Loya, S., **Aziz, A.**, & Chatwin, C. (2014). A Service Oriented Approach for Guidelines-based Clinical Decision Support using BPMN. Studies in health technology and informatics, 205, 43-47.
4. **Aziz, A.** Rodriguez Loya, S., Chatwin, C. and Birch, P. (2010). Towards interoperability: electronic healthcare system using service oriented architecture. In: International Conference on the Implementation of Electronic Health Records, 26th October 2010, London.

Part I: Introduction to the Research

Chapter 1 Introduction

Chapter 2 Evidence Based Clinical Decision Support Systems and Service Oriented
Architecture -A Review of Literature

Chapter 1

Introduction

Chapter 1

INTRODUCTION

1.1 Introduction

Over the past two decades, a significant number of healthcare service providers have moved towards using large-scale and sophisticated distributed systems to streamline their business and health-related processes. The research disciplines of Clinical Informatics and Software Systems Engineering have been pivotal in understanding and disseminating knowledge related to the design and use of these IT systems. Research produced by examining these systems, has identified that a major challenge in successful implementation of these systems is the lack of interoperability between the various systems that provide patient data for Clinics, Hospitals, Pharmacies and Patient Self-management Systems. Another challenge with these heterogeneous systems is that they continually evolve in response to changing market trends for healthcare service technology and the evolving nature of medical practice research, resulting in multiple formats of medical data that give rise to integration issues. Data exists in the most complex forms in healthcare IT systems. A lack of consistency between these systems leads to inefficient data management thus inhibiting the benefits that can be realized by the use of Electronic Healthcare. Medical data must be provided keeping in view fundamental issues of Security, Accuracy and Rapid Response Time. In the recent years, most of the modern healthcare IT solutions have some level of Clinical Decision Support (CDS) capabilities to assist the clinician in making patient-specific decisions at the point of care. However these CDS systems are tightly coupled with the vendor-specific technologies and platforms, inhibiting their integration with clinical systems that are supported by other technology platforms. A significant amount of research has been conducted to identify challenges and opportunities for integration of CDS Systems as reusable services in an architecture that is platform-agnostic, thus promoting reuse and sharing of such services within and across a healthcare

organization. This research provides a framework for design and implementation of evidence based clinical decision support which is based upon translating the clinical needs into standardized services in order to acquire interoperability among different systems.

1.2 Motivation of the Research

One of the fundamental capabilities of healthcare information technology is achieving interoperability among the various components that together provide a healthcare service. In case of Clinical decision support systems, these components include Electronic health record applications, patient database, clinical guidelines or pathways, clinical knowledge base and end user interfaces for clinicians. In order for these components to work successfully to provide the desired outcome, there is a need for an infrastructure, in other words, an architecture that supports the orchestration of services to provide CDS. Service Oriented Architecture is one such approach that is based on a web services infrastructure to automate an organization's business processes and provide effective communication mechanisms for all the components to work collectively to deliver the organizational goals. This research study is conducted to create an integration framework based on SOA principles and an implementation of clinical best practices which are derived from evidence based medicine. The integration solution implements standardized clinical practice guidelines to provide an enriched CDS capability. This research applies the concept of Business Process Management in the healthcare domain, where the clinical processes are modelled and executed using BPM tools and technologies.

1.3 Research Objectives:

The objectives of this research are listed below:

1.3.1 Evidence Based Medical Knowledge Integration

Evidence based medicine (EBM) is the application of the results of the latest medical research, clinical trials and medical expertise to provide improved healthcare outcomes. The knowledge gained by the process of EBM is critical to medical practice, as it permits the physicians to embed the latest research into their routine practice. Availability of this

scientific evidence to a physician during routine clinical practice is limited given its complex nature and limited availability of technology. Enabling evidence based knowledge integration with clinical applications involves research insights into Clinical Practice Research and Clinical Informatics. A significant level of understanding of evidence based clinical practice and how this knowledge can enable an enriched informatics solution is needed.

1.3.2 Integration of CDS with Healthcare Information Systems

Clinical Decision Support systems depend largely on medical data collected in healthcare IT systems such as patient demographics, laboratory results, order entry systems etc. This makes it necessary to provide a communication mechanism among these systems and the CDS systems. Integration mechanisms such as Enterprise Service Bus and SOAP based web service communication are vital to provide the desired communication. However health IT vendors provide CDS functionality as a part of their EHR solution, which makes it difficult to be shared and reused. There is a need for research focusing on developing CDS functionality as independent modules, as the knowledge engrained in CDS functionality can be widely disseminated in healthcare IT systems being used by various healthcare organizations.

1.3.3 Automating Clinical Workflows

A clinical workflow is a step-by-step sequence of actions in the process of healthcare service delivery. A key focus of this research is to automate a clinical workflow or a clinical pathway by modelling and executing the knowledge embedded in the clinical pathway. To promote uniform practice in terms of latest evidence base, standardized clinical practice guidelines created by national clinical research organizations are selected to provide case studies for this research.

1.3.4 Adoption Issues

The challenge of adopting technology by many healthcare organizations remains a key barrier to successful implementation of HIT. The primary reason for this problem is the complex nature of these IT systems and the large communication gaps between clinicians and software developers while designing this software. This is a clear research gap in

addressing the challenges faced by managers and physicians for using IT systems for their routine administrative and clinical processes. By involving clinicians in the process of designing IT solutions, major obstacles to adoption and use can be overcome.

1.3.5 Managing Organizational Resources

A healthcare IT solution system such as a CDS System, must accommodate clinical as well as non-clinical processes. This is particularly important in the case of emergency departments in hospitals as it involves allocation of resources as well as managing clinical data in a time-constraint environment. The focus of this research is to design a system capable of managing a hospital's resources such as physicians, nurses and managers in addition to clinical processes.

1.3.6 Addressing Interoperability by use of SOA

Interoperability remains a critical challenge for healthcare IT solutions. Various research studies conducted in this area have stressed the need for an interoperable architecture. A Service Oriented Architecture based clinical decision support system is composed of interoperable and loosely coupled web services that implement diagnostic and treatment guidelines. By following the SOA principles, these guidelines can be shared and reused across multiple technological platforms.

1.3.7 Standards Integration

To promote exchange of healthcare data across the boundaries of a healthcare facility, the aim of the research is to implement standard interfaces using HL7 Decision Support Service.

1.3.8 Open source Tools & Technologies in Healthcare

A large number of open source tools have been introduced in the recent years to promote cost effective solution to healthcare service delivery. The aim of this research is to utilize such tools and technologies to implement clinical decision support.

1.4 Research Questions

1. How can Business Process Management and Workflow Technology be applied in healthcare service delivery?
2. Does Service Oriented Architecture provide an integration solution to healthcare data for Clinical Decision Support at the point of care?
3. How an SOA based architecture solution improves CDS at the point of care by automating the clinical workflows? Is the proposed architecture able to support organizational process to improve care delivery?
4. How can we ensure that standards such as HL7 are followed by using the proposed architecture solution?
5. How does this architecture leverage Genetic Information to facilitate CDS at the point of care?
6. Does the CDS Framework fulfil the requirement in terms of evaluation for a sub second response?

1.5 Achievements

This thesis has resulted in the following achievements:

1. **SOA based Integration Solution:** This research has resulted in a SOA based architectural framework named “**CDS Framework**” that orchestrates multiple components that work in collaboration to provide CDS functionality at the point of care.
2. **Standards Based Implementation** This study has employed standards such as HL7 Decision Support Service and HL7 Virtual Medical Record, which are the industry specification for uniform exchange and representation of CDS knowledge.
3. **Guidelines based CDS:** To provide the latest evidence in medical conditions like Chronic Obstructive Pulmonary Disease, Lung cancer and public health matters like New born screening for Cystic Fibrosis, guidelines published by the Department of Health UK’s, National Institute for Health and Care Excellence (NICE) have been implemented. The aim was to embed these guidelines while defining the knowledge base for CDS, so that this information is available as part of the routine workflow for a physician in an automated matter. This will save precious time in terms of diagnosis and

early intervention as the physician will not need to consult separate resources for the latest evidence during the process of a patient-physician encounter.

- 4. Managing Clinical Resources:** This research has presented a mechanism for managing human resources in critical healthcare scenarios such as emergency care. This is enabled by a Human Task Management component, which can be integrated with the CDS Framework as needed by the healthcare organization.

1.6 Thesis Structure

Part I: Introduction to the Research

Chapter 1 INTRODUCTION

Brief:

This Chapter provides an introduction to the research. An overview of the Concepts relevant to this research is provided. The research aims and objectives are explained in detail. The research questions and Achievements of this research are explained.

Results:

The contributions made by this research exercise are provided. The critical research areas are identified.

Chapter 2 EVIDENCE BASED CLINICAL DECISION SUPPORT SYSTEMS AND SERVICE ORIENTED ARCHITECTURE -A REVIEW OF LITERATURE

Brief:

This chapter provides a survey for the trends in software architecture approach and the current trends in CDS implementation architectural approaches. Key research concepts namely Clinical decision support, evidence based medicine and healthcare standards are explained. An overview of Service Oriented Architecture in healthcare is presented. Additionally, a survey of the use of BPM and Workflow Technologies in Healthcare is presented.

Results:

Preliminary evaluation of the studies show that there is profound potential for Service Oriented Architecture based implementations for Clinical Decision Support at the point of care.

Part II: Architecture Design and Implementation**Chapter 3 GUIDELINE REPRESENTATION AND EXECUTION MODEL-TOOLS, TECHNOLOGIES AND DEVELOPMENT OF THE CDS FRAMEWORK*****Brief:***

This chapter covers the CDS Framework developed for this project. The architecture model and the guidelines representation using BPMN and execution using Open Source components such as ESB SwitchYard exploiting Service Component Architecture are presented.

Methods:

The Service Composite architecture that exploits the SOA principles is used to realize CDS capabilities for healthcare system. A plugin using Java EE is designed to interface with Tolven eCHR™. Tolven eCHR™ is used as an interface for the physician. The SOA based data transformation is executed by Enterprise Service Bus, SwitchYard.

Results:

The developed architecture successfully implements SOA principles. Secondly, SCA composites of the clinical workflows are available as executables. Healthcare Process modelling is done using BPMN.

Part III: Implementation Case Studies in Healthcare**Chapter 4 TESTING AND EVALUATION OF CDS FRAMEWORK-CASE STUDIES FOR IMPLEMENTATION OF CLINICAL GUIDELINES (Clinical Practice)**

Brief:

This chapter provides two case studies for implementation of the CDS Framework described in Chapter 3. The CDS Framework is tested using 1) NICE Guideline for COPD and 2) NICE's guideline for Lung Cancer

Methods:

Using BPM Process lifecycle (for COPD case study) and Agile Business Rules Methodology(for Lung Cancer case study), the guidelines are implemented as processes and then executed as SCA Composites using the CDS Framework.

Findings:

The guidelines were successfully implemented using the BPM approach to guidelines authoring and modelling. The SCA composites for the processes are available as Web Services and adhere to SOA principles. Both the implementations were evaluated using performance testing against the standards for effective CDS performance.

Chapter 5 TESTING AND EVALUATION OF CDS FRAMEWORK-CASE STUDY FOR ENABLING GENETIC DATA FOR CDS AT THE POINT OF CARE (Genetic Testing Implementation)

Brief:

This chapter utilizes the CDS Framework for providing Genetic Testing-guided CDS at the point of care within the clinical workflow. The NICE Guideline for Newborn screening for Cystic Fibrosis is implemented using the CDS Framework.

Methods:

Genetic data for the patient is collected and maintained in the EHR. Decision rules are developed governing the clinical decision support functionality. Inferences based upon the genetic data of the patient are provided to the physician at the point of care.

Findings:

CDS Framework provides inferences based upon the DNA test results for the patient. The service is tested against CDS Performance evaluations.

Chapter 6 TESTING AND EVALUATION OF CDS FRAMEWORK-CASE STUDY FOR COLLABORATIVE HEALTHCARE MANAGEMENT (Organizational Practice)

Brief:

This chapter provides the BPM solution to healthcare organization's management of clinical as well as non-clinical processes. To ensure evidence-based medical practice in Emergency Department, a Human Task Management service is designed to model the process of coordination of ED resources based on the UK's NICE Clinical guideline in managing the care of acutely ill patients

Methods:

"Pattern-Based Cycle for E-Workflow Design" has been adopted as the methodology this cycle consist of four steps specifying definitions of e-workflow's 1) functional perspective, 2) organizational perspective, 3) behavioural perspective and 4) informational perspective. The jBPM Human Task Management Service, jBPM Console is utilized.

Findings:

Facilitating an ED with evidence-based guideline-cantered sequences of actions, this chapter provides an enriched outlook of the patient flow ensuring a decrease in the treatment gaps, reducing redundant tasks and integrating of human work with the available information systems.

Part IV: Conclusion

Chapoter 7 CONCLUSION ANF FUTURE DIRECTIONS

This Chapter presents a thesis summary, benefits of using the CDS Framework, limitations of this research and Future directions.

Chapter 2

Evidence Based Clinical Decision Support
Systems and Service Oriented Architecture -
A Review of Literature

Chapter 2

EVIDENCE BASED CLINICAL DECISION SUPPORT SYSTEMS AND SERVICE ORIENTED ARCHITECTURE - A REVIEW OF LITERATURE

2.1 Introduction

This chapter provides a detailed study of the literature encompassing current trends for architecture capable of providing CDS for evidence based medicine. A detailed view of the healthcare IT systems is provided. The focus is then pointed to Clinical decision support and the system architecture required for implementing a Service oriented architecture approach for CDS systems.

2.2 Chapter Organization

The chapter is organized as follows. Section 2.3 describes an overview of Health information technology. 2.4 describes Clinical decision support and implementation challenges and approaches. Section 2.5 describes SOA in detail. 2.6 introduces research related to Business Process Management. Section 2.7 describes evidence based medicine and clinical guidelines. 2.8 provide a detailed description of healthcare standards. 2.9 briefly introduce the research areas for this thesis. 2.10 describe the research methodology. Section 2.11 presents the implementation strategy. Finally 2.12 presents result and 2.13 concludes the chapter.

2.3 Overview of Health Information Technology (HIT)

“Health information technology (HIT) is the area of Information Technology involving the design, development, creation, use and maintenance of information systems for the healthcare industry.” [1] The primary aim of Healthcare IT Systems is to provide care to the healthcare domain customers, *the patients*. A critical factor in the use of HIT is whether it improves the quality of care provided to the patients [2]. The Healthcare IT systems are designed such that various actors involved in the healthcare service delivery process such as physicians, nurses and hospital managers, are all facilitated by the use of computer software to meet this aim. The healthcare IT systems should deliver the functionality to support large patient data sets, clinical processes (ordering and decision making) and reporting mechanisms to augment the care delivery process. The healthcare delivery process is mainly composed of clinical and non-clinical transactions. An information system must support these transactions in a timely and robust manner. Some examples of healthcare IT systems are Patient Administration Systems (PAS) for maintaining and managing patients’ demographics data, Laboratory Information Systems (LIS) support laboratory operations, Picture Archiving and communication Systems (PACS) provide online access to clinical imaging thus eliminating manual storage and communication of medical images.

2.3.1 Electronic Health Record:

A key information system that combines results of various health information systems in HIT is an Electronic Health Record (EHR) system or application.

According to HIMMS the definition of an EHR is provided below¹:

“The Electronic Health Record (EHR) is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports. The EHR automates and streamlines the clinician's workflow. The EHR has the ability to generate a complete record of a clinical patient encounter - as well as supporting other care-related

¹ <http://www.himss.org/library/ehr/>

activities directly or indirectly via interface - including evidence-based decision support, quality management, and outcomes reporting.”

A comprehensive EHR is composed of the following functionalities [3] as shown in Table 1.

Table 1 Core functionalities of an EHR

Functionality	Examples
Clinical documentation	Patient demographics, medication lists, problem lists, discharge summaries
Decision support	Clinical guidelines, Alerts and reminders, Drug-drug interaction alerts
Order entry	medical imaging tests, Laboratory tests, prescriptions
Test and imaging results	Consultation reports, lab tests results, radiology reports

Given the diverse nature of information to provide the required functionalities, an EHR application not only needs to communicate within a healthcare organization, but must also allow swift and secure communication with external healthcare applications and data sources located over distant geographic locations. This directly necessitates the critical need for interoperability among these multiple information systems. Thus there is a strong requirement for an architecture that facilitates these communications in an interoperable manner.

2.3.2 The challenge of Interoperability:

Interoperability is defined as,

“The ability of two or more systems or components to exchange information and to use the information that has been exchanged”²

According to the HL7 EHR Interoperability Work group [4], in the context of healthcare organizations and applications, interoperability can be categorized as the following three types:

- 1. Technical Interoperability:** Technical interoperability is used synonymously by many researchers as *Functional Interoperability* or *Syntactic Interoperability*. In the healthcare domain, technical interoperability is related with the “conveyance of data”, by means of

² <http://www.healthit.gov/>

hardware, transmission and accessibility. It does not refer to the content and meaning of data that is being transferred across application but rather the mechanism of transfer.

- 2. Semantic Interoperability:** The semantic interoperability is related to the “ability of information shared by the systems to be understood.” This deals directly with data representation and common semantic interpretation that are well documented and understood by both the sender and the receiver applications. Classifications systems and standardized clinical nomenclature are utilized to ensure semantic interoperability in healthcare applications.
- 3. Process Interoperability:** The process interoperability concept is a critical success factor for successful integration of various components that together provide the IT solution for a healthcare environment. Process/social interoperability takes into account the organizational, temporal, situational aspects of healthcare environment. IT ensures timely, event or sequence-oriented coordination that is required to fulfil healthcare practice.

2.4 Introduction to Clinical Decision Support

“Clinical decision support (CDS) systems provide clinicians, staff, patients, and other individuals with knowledge and person-specific information intelligently filtered and presented at appropriate times, to enhance health and health care” [5]. It is a HIT functionality that constitutes features like diagnosis, drug-drug interactions, and treatment options. Evidence has shown that CDS has been widely adopted to increase patient safety and improve clinical outcome [6]. A number of maturity models have recognized the importance of CDS as a key functionality for the success of Health Information Technology. The Electronic Medical Record Adoption Model (EMRAM) established by the Healthcare Information and Management Systems Society (HIMSS) [7] The Electronic Healthcare Maturity Model (eHMM) developed by Quintegra [8], and the Electronic Patient Record (EPR) maturity model established by the United Kingdom National Health Service (NHS) [9,10]

A typical CDS System consists of four components namely

- 1. Data input:** Includes patient data such as problem lists, demographics details

2. **Inference engine (decision engine):** A decision engine is a reasoning mechanism with rules to process the input patient data.
3. **Clinical Knowledge base:** A knowledge base consists of rules usually in the IF-THEN format. For example for a diagnosis decision support system it will contain knowledge like IF (symptom 1, symptom2), THEN (diagnosis 1)
4. **Data output:** It is the result of the CDS process that is provided to the user. A workflow of a CDS process is shown in Figure 1.

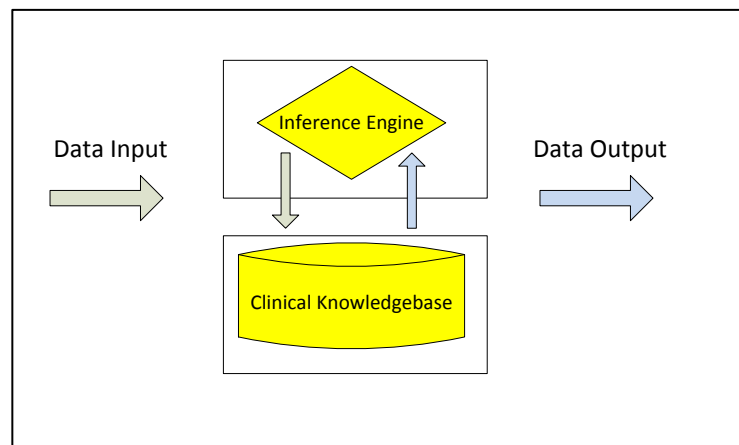


Figure 1 Components of a CDS System

2.4.1 CDS and Meaningful Use Criteria:

The United States Centres for Medicare & Medicaid Services (CMS) Incentive Programs introduced Meaningful Use certification and incentives for providers who meet to the criteria. To promote a standards based and uniform use of EHRs, the Obama Administration introduced software certification with the goal of assuring that the EHRs provided the basic quality, safety and efficiency standards [11]. The timeline of Meaningful Certification was divided into three phases starting from 2009 to 2016. The second stage of Meaningful Use criteria necessitates the use of Clinical decision support to enhance care processes. The Evidence based CDS interventions must support either one or a combination of the following key features in the EHR implementation:

1. Problem list
2. Medication list
3. Medication allergy list
4. Demographics
5. Laboratory tests and values/results
6. Vital signs

The introduction of Meaningful Use certification has been seen to promote the adoption of EHRs across the U.S and CDS has been a vital part of this certification.

2.4.2 Importance of CDS in Health Information Technology

Kawamoto [12] conducted a systematic review to identify the contribution of Clinical decision support for successful and improved clinical practice. This systematic review resulted in the following key features of CDS which provide improved clinical outcome:

1. Automatic provision of decision support as part of clinician workflow
2. Provision of decision support at the time and location of decision making
3. Provision of a recommendation, not just an assessment
4. Computer based generation of decision support
5. Justification of decision support via provision of research evidence

The above identified features necessitate the following key functionalities of a computer based clinical decision support:

1. A system capable of automating a clinical workflow, so that the results of best research evidence can be incorporated into the workflow as knowledge base.
2. The physician must be provided with an interface to enter key data and receive results from a decision engine in a human readable form.
3. In addition to decisions such as diagnosis, the system must additionally provide the sequence in treatment for example; recommendations to the physician about the next actions to perform once a diagnosis decision has been provided.

4. The clinical decisions must be provided as part of a computer based reasoning and inference software.

2.4.3 Architecture for CDS Implementation

The Clinical Decision Support Consortium (CDSC) [13] has recognized Service Oriented Architecture as a favourable architecture approach when designing computerized CDS systems for healthcare settings. By using SOA, independent services can be coordinated to deliver the required functionality of collecting patient data, calculating results and delivering them to the physician at the point of Care. A number of examples stressing the benefits of SOA based approach in architecture for CDS exist. One example of such systems is SANDS [14], Service-oriented Architecture for NHIN Decision Support. SANDS Architecture is composed of a standard based interface between the physician information system and Decision Support System. The services are centralized allowing management of the clinical knowledge base and patient data.

2.4.4 CDS Integration Approaches - A historical perspective:

Write and Sittig [15] have identified four different integration approaches in terms of architecture:

1. **Standalone decision support systems:** With the advent of artificial intelligence and expert systems, these systems would take clinical parameters as input and provide suggestions for diagnosis and treatment. Example systems include MYCIN [16], and ATTENDING [17].
2. **Integrated systems:** Beginning in 1967, the integrated CDS involves connecting CDS Systems within other HIT systems such as computerized physician order entry and Electronic Health Record applications. Examples of such systems include Regenstrief Medical Record System [18] and HELP system. [19]
3. **Standards-based systems:** Owing to the tightly coupled nature of integrated approach for CDS within other systems, the problem of sharing CDS knowledge was regarded as a critical obstacle for the success of CDS Systems. In 1989, the Arden syntax [20-22], was introduced that encoded clinical rules for CDS in Medical Logic Modules (MLMs). This

standard improved the sharing of clinical knowledge base across multiple settings however lack of terminology interoperability has still lead to its limited use.

- 4. Service models:** Over the past decade, there has been an increase effort in separating the clinical information systems and CDS modules by implementing standards based interfaces, commonly termed as Application Programming Interfaces (APIs). Examples of such efforts include Sharable Active Guideline Environment (SAGE) [23] and SEBASTIAN [24] which uses a standards-based patient model based on the HL7 RIM.

2.4.5 Challenges for implementing CDS

Sittig [25] have identified the following grand challenges for implementing successful CDS. These challenges are listed in the Table. 2.

Table 2 Summary of the grand challenges of clinical decision support along with their mean rank and the standard deviation of that ranking (Sittig [25])

Grand challenge description	Mean ranking	Standard deviation
Improve the human–computer interface	2.89	2.71
Disseminate best practices in CDS design, development, and implementation	3.33	1.87
Summarize patient-level information	3.67	2.06
Prioritize and filter recommendations to the user	4.56	2.96
Create an architecture for sharing executable CDS modules and services	5.44	2.30
Combine recommendations for patients with co-morbidities	5.89	2.20
Prioritize CDS content development and implementation	6.00	2.96
Create internet-accessible clinical decision support repositories	6.89	1.69
Use free text information to drive clinical decision support	7.89	1.27
Mine large clinical databases to create new CDS	8.44	3.00

Although all the challenges listed by Sittig [25] are significant in their unique ways, for the purpose of system’s architecture research, the challenge **“Create an architecture for sharing executable CDS modules and services”**, is identified to be critical when designing and implementing a hospital wide CDS system.

Additionally, other authors have highlighted problems with current architecture approaches for CDS, Paterno [26] have identified long time required to receive a CDS response as a critical factor.

2.5 Service Oriented Architecture

The IT component of Enterprise Architecture is concerned with the development of a technological infrastructure to address information and communication needs of an organization. The selection and use of a particular IT strategy heavily influences the performance and business outcome of an organization. SOA has been widely adopted as a mechanism to implement the IT strategy of an enterprise. By using a SOA based approach, various business services of the organization are implemented as executable and sharable software services using the techniques of service reusability, scalability, discoverability etc. These software services realize the business operations and are accessed using web based interfaces.

“Service-Oriented Architecture is an IT strategy that organizes the discrete functions contained in enterprise applications into interoperable, standards-based services that can be combined and reused quickly to meet business needs.”-*Bill Roth, Microsoft BEA Systems*

Web services are the building blocks of a Service oriented architecture. As described by the World Wide Web Consortium (W3C) “Web services are client and server applications that communicate over the World Wide Web’s (WWW) Hypertext Transfer Protocol (HTTP), web services provide a standard means of interoperating between software applications running on a variety of platforms and frameworks”. [27]

2.5.1 Core Characteristics of SOA:

The principles of service-orientation [28] are listed as follows:

- 1. Standardized Service Contracts:** The functionality of a web service is contained in a Service contract. It specifies all interactions between the service users and service providers.
- 2. Service Loose Coupling:** Coupling refers to the sum of dependencies between interacting systems. Loosely coupled services represent a low number of known and

manageable services. The more loosely coupled a system is, the more flexible and extensible it is.

- 3. Modularity and Granularity:** Service Modularity refers to the self-containment feature of a web service. Granularity refers to coarse-grained or fine-grained aspect of a web service. Coarse grained web service allows a single operation to provide multiple functionality from a web service. A coarse-grained service reduces complexity and network transmission costs.
- 4. Service Autonomy:** Autonomy refers to the design, implementation and deployment of a web service independent of the other web services for a software system.
- 5. Service Reusability:** Service reusability principle allows the web services to be shared and reused across the enterprise. The design of these services conforms to the principle of separating business logic and implementation details so that the services can be reused independent of the technological platform.

2.5.2 Enterprise Service Bus:

Enterprise Service Bus is defined as "a style of integration architecture that allows communication via a common communication bus that consists of a variety of point-to-point connections between providers and users of services." [29]. ESB is a middleware application often used as an infrastructure service with the goal to allow interoperability among several components of a software architecture [30] [31]. The core features of an ESB are data connectivity through adapters via internet protocols like Hypertext transfer protocol (HTTP) by leveraging SOAP, XML based communication mechanisms. It enables intelligent routing of data from senders to relevant receiving applications, data transformation and data flow coordination.

2.5.3 SOA in Healthcare IT:

Typical service oriented architecture for the design of a healthcare enterprise is based upon SOA layers as shown in Figure 2. Interfaces are designed by categorizing the system users after access rights and privileges are decided. Use cases and information flow of the required data guides the design of the system according to user types.

- 1.** The Application Interface layer lies at the top of the system architecture deriving medical reports from the business logic systems.

2. Health related data is extracted from the Data Sources. Domain Specific Web Services (Composite WS) are designed and are communicated across the systems through the Enterprise Service Bus.
3. The Enterprise Service Bus acts as a backbone infrastructure using standards based adapters and interfaces ensuring security, policy and consistency among the web services being requested and consumed by applications. Using the HL7 Integration Engine, the data is communicated across the multiple business systems' interfaces for uniform data formats. To ensure Semantic Interoperability common Clinical Terminology standards SNOMED CT, LOINC etc. are used. For web services data transfer across the systems, SOAP communication protocol is widely used [32] [33].

These domain specific web services can be hosted on the premises i.e. in the hospital IT infrastructure as well as in a cloud based environment [34].

Several methodologies were introduced to implement SOA based solutions. For example Service Oriented Modelling and Architecture (SOMA) from IBM [35], Service Oriented Analysis and Design (SOAD) also from IBM [36], Thomas Erl's methodology [28].

2.5.3.1 Service Component Architecture:

To address the complexities of implementing SOA, an industry standard called Service Component Architecture (SCA) was introduced by OASIS, Open Composite Services Architecture. SCA is a set of specifications designed for building distributed applications based on SOA. "SCA represents a high level of abstraction and addressing complexity and reusability of software. SCA hides the complexity such as specifying security, reliability and other quality of service elements from the application code" [37]. From a conceptual point of view of SCA, business functionalities are provided as multiple services which are assembled together (*as composite applications*) to implement a business requirement.

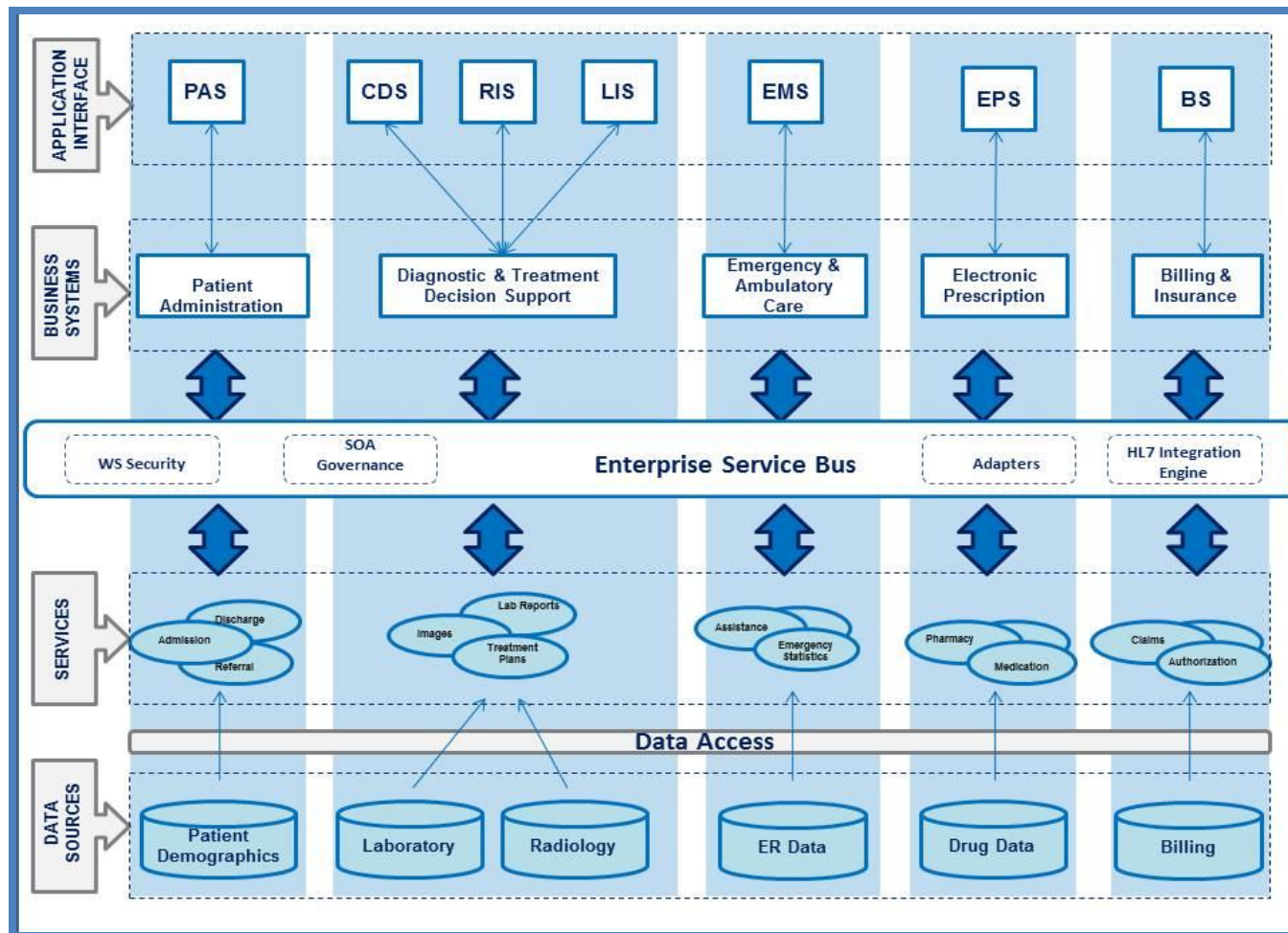


Figure 2 A high level view of SOA based Healthcare IT Architecture

An SCA Assembly model consists of XML-based artifacts. A composite application holds the services [38]. Each composite contains components that represent a separate functionality and can be wired together for combined functionality of a business. An SCA Runtime is a deployment environment, usually a part of the Enterprise Service Bus [39], with XML representations of components, services references and configuration for interacting applications and external system. The SCA Assembly Model is depicted in Figure. 3.

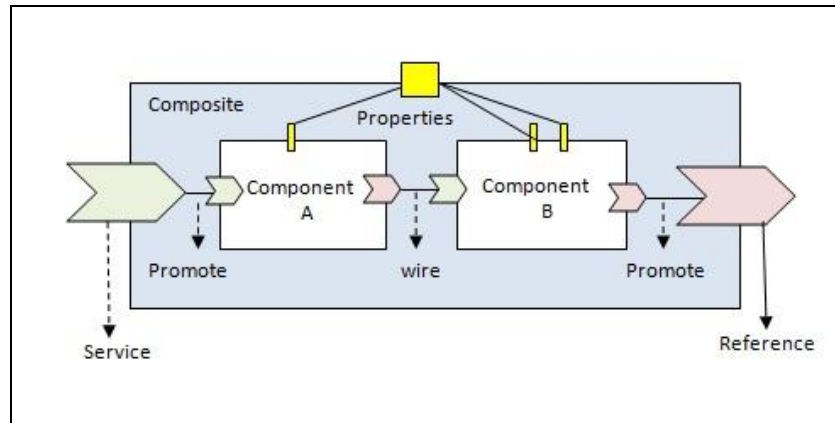


Figure 3 SCA Assembly Model

2.6 Business Process Management in Healthcare IT :

“Business process management (BPM) is an organised approach to defining, executing, managing, and refining business processes, which can improve the efficiency of business operations.” [40] [41]. Business processes typically involve both machine and human interactions, integrate with various internal and external systems, and include both static and dynamic flows that are dependent on both business rules and technical restrictions. Among the 6 core elements of BPM : “1) Strategic Alignment 2) Governance, 3) Methods, 4) Information Technology, 5) People and 6) Culture”, governance allows appropriate and transparent accountability in terms of roles and responsibilities of the different actors involved in a process [42]. HCO’s multidisciplinary operational nature requires organizational and medical processes to function conjointly to achieve its goals. Hoffer [43] identifies “Team factors including communication, clarity of roles, and leadership” as a critical contributor to manage the complex operational nature of an HCO.

BPM in Banking, Finance and Insurance is focused on “risk reduction, optimizing outcomes, and delivering superior user and customer experience.”³ The building block of BPM is a business process. A business process is a set of synchronised tasks and activities that lead to achieving an organizational goal. The progression from one step to the next of guided by business rules. A business Rule is defined as “a statement that defines or constrains some aspect of the business. It is intended to assert business structure or to control or influence the behaviour of the business. The business rules that concern the project are atomic – that is, they cannot be broken down further” [44]. Business rules are expressed in a language that all participants in a business activity can understand and are implemented by Business Rules Management System (BRMS) [45]. Some of the most common formats for authoring business rules include: “if-then rules, decision tables, decision trees, scorecards and custom languages. The If-then format is the preferred type of language for condition-action rules “[46].

A critical requirement for an organization to start BPM practices is Business Process Modelling. Business Process Models graphically represent business processes [47].

Applying the concept of BPM in healthcare, the term “*Healthcare Process Management*” is used for clarity. A healthcare organization functions based upon the clinical and administrative processes that together provide a healthcare goal, hence making it a process-centric organization. Information systems that automate an organization’s functionality based upon its processes are called Process aware Information Systems [48]. BPM facilitates connection of user focused capabilities with technical capabilities [49].

Helfert [50] conducted a study to identify the challenges of applying the practices of BPM in healthcare in the Irish health sector. He identified a number of factors that are critical to the success of BPM in healthcare, firstly, addressing domain-specific issues e.g. complexities inherent in healthcare processes and secondly, appropriate management practices like time management, change management enabling human interaction with a computerized workflow. This study identified Business Process Modelling to address the above mentioned issues. Becker [51] have proposed a workflow based solution for integrated care in the US healthcare processes.

³ <http://www.bpm.com/bpm-in-banking.html>

2.6.1 The Potential of SOA and BPM Combination:

By combining the principles of Business Process Management and Service Oriented Architecture, organizations can implement a strategic alignment of technology with its success goals [52]. The business processes modelled by BPM can be swiftly implemented using SOA. Given the nature of BPM, that it is business process driven, IT-driven nature of SOA can result in combined benefit of organizational agility [53]. According to the results of a survey conducted by Gartner Inc., organizations are more likely to adopt BPM and SOA together to realize the combined benefits of meeting the aim of loosely-coupled and reusable IT capabilities that can be shared across organizational boundaries [54]. In a red paper published by IBM, [55] an implementation strategy of BPM in an organization along with SOA is presented. This study presents a BPM enabled by the SOA methodology. The five phases are presented in Table 3.

Table 3 BPM enabled by SOA Methodology Phases by IBM [55]

Stage	Description
1. Envision	Identifying process capabilities and processes that support future business capabilities
2. Assess	Assessing current processes, process performance, and process enablers (technology, organization, and knowledge) to develop the requirements for future business processes
3. Define	Designing future business processes, defining future process performance, and supporting process enablers (technology, organization, and knowledge)
4. Execute	Building, testing, and deploying business processes, performance monitoring and reporting, and supporting process enablers (technology, organization, and knowledge)
5. Optimize	Operating, monitoring, and managing operational processes and their supporting process enablers (technology, organization, and knowledge)

2.6.2 Workflow Technologies in healthcare

To realize Business Process Management for IT enabled business processes in an organization, Workflow Management Systems (WfMS) have been widely implemented. According to the Workflow Management Coalition (WfMC) [56], workflow is defined as "automation of a business process, in whole or part, during which documents, information, or tasks are passed from one participant to another for action, according to a set of procedural rules." Dwivedi [57] presented a dynamic connection between healthcare, workflow and internet technologies, and proposed that workflow management systems can

significantly influence the performance and outcome of a healthcare service. For the clinical decision support area of healthcare IT, [58] identified that workflow tools have a potential to significantly improve healthcare delivery by augmenting the clinician's decision making in the form of alerts and reminders, a functionality of CDS.

Over the past decade various efforts have been made to formalize the encoding of processes to achieve synchronization in implementing workflow technologies. These standards are listed in Table 4.

Table 4 Popular Standards for Workflows

Standard	Organization, Year	Description
BPEL (WS-BPEL)	OASIS (2007)	Specifies business processes with web services
BPMN	Object Management Group, 2005	Graphical representation for Business processes
XPDL	Workflow Management Coalition (WfMC), 1998	Specification for exchanging business process definitions between different workflow products
UML	Object Management Group (OMG), International Organization for Standardization (ISO) 1996	Visual design of a software system

2.7 Evidence Based Medicine and Clinical Guidelines:

“Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients” [59].

The implementation of Evidence based medical (EBM) practices at the point of care confirms the best possible clinical care at low costs [60]. EBM encompasses best practice and standardization for clinical practice. These standards are based on scientific evidence from the Medical literature, clinical trials and the latest research providing the physician with adjudicated data to make informed decisions when formulating patient-specific diagnosis and treatment strategies. A practical implementation of EBM is Clinical Guidelines (CGs). Clinical practice guidelines (also called pathways) assist a healthcare practitioner with managing individual patient conditions. [61] Identify challenges to implementing successful CDS within the healthcare workflow. From an architectural point of view the following two issues are critical,

1. Publish best practices in CDS design and implementation
2. Create an architecture for sharing executable CDS modules and services.

To disseminate best clinical practices integrated into a CDSs, clinical guidelines have been incorporated into the CDS functionality of an application used by a physician [62]. CGs represent a health care procedure as a systematically developed process defining the necessary information in a sequence guided by clinical rules that are appropriate for specific patient needs. Guidelines promote interventions during clinical practice to replace the use of inefficient medical practices with evidence-based practices to improve clinical outcome. Computerized guidelines have been successfully implemented for various health conditions such as liver transplant [63] [64]

To promote practice of evidence based medicine and clinical guidelines, efforts have been made on national levels such as Agency for Healthcare Research and Quality's (AHRQ) in the US⁴ and National Institute of Health and Care Excellence in the UK⁵. These agencies have the following goals:

1. Publish evidence based guidance for health and social care practitioners. These guidelines are developed using the current research in clinical practice, medical science research and clinical trials and are available publicly.
2. Update the guideline as new evidence become available to guide latest trends in medical practice.

2.8 The need for healthcare standards

For an SOA based Health IT implementation, semantic interoperability is an essential feature [28]. A healthcare organization such as a National Health Service trust in the UK typically consists of units such as hospitals, clinics and General practitioner surgeries. Medical data for patients is scattered across these units. The information systems in use by one unit may differ from the other. For example, a GP system may be provided by one

⁴ <http://www.ahrq.gov/>

⁵ <http://www.nice.org.uk/>

vendor whereas the Accident and Emergency system in use in the hospital is provided by another. During the care cycle, a patient may be associated with more than one departments or units. Because of differences in the product design (*i.e. vendor-specific*), transferring patient data across these units can result in data inconsistencies and is therefore a major issue in terms of patient safety.

Healthcare standards provide standard data exchange models and schema across applications regardless of what technology is used to develop these systems. Effective communication requires that information sending and receiving applications share a common “reference framework” that facilitates interaction. The goal of standards is to address the issue of interoperability between disparate healthcare IT systems.

2.8.1 Healthcare Standards Development Approaches

There are four standards development approaches:

1. **Ad hoc:** when a group or community of practice agrees to use a certain standard without formally publishing it
2. **De Facto:** disseminated by end user and market acceptance
3. **De Jure:** Government imposed standards
4. **Consensus:** Different organizations sit together to address a common problem and propose a standard that is agreed upon by the participating parties. HL7 standards are developed using this approach.

2.8.2 Categories of Healthcare Standards

Healthcare information standards usually result from a collaborative effort between interested workgroups who have identified the need for these standards based upon research, clinical trials, use of HIT etc. These groups comprise of physicians, project managers, data analysts, software architects, chief information officers. Based on the use of standards, the following categories are defined:

1. **Messaging and Data interchange:** Specify the format, data elements and structure of data to be interchanged between different systems.

- 2. Terminology Standards:** These are vocabularies or nomenclature used to described clinical and non-clinical concepts in healthcare domain. For example, diseases, orders, lab results.
- 3. Document Standards:** These standards specify the information required to populate clinical documents, like for example in CCD, the patient name, demographics, discharge summaries or consultation notes.
- 4. Conceptual Standards:** These specify the context of clinical data needed to be transmitted across systems and applications. These include information models like HL7'S Reference Information Model (RIM)
- 5. Application Standards:** These standards specify the human-computer interaction for a software healthcare system. For example, Single Sign On, CPOE etc.
- 6. Architecture Standards:** Architecture standards deal with the mechanism of clinical and non-clinical knowledge storage and distribution across multiple systems. Examples are surveillance systems for potential disaster management in health. The categories for healthcare standards, example standards and the organizations are listed in Table 5

Table 5 Categories of standards for health information exchange

Category	Example Standard	SDO
Data Exchange/Messaging	HL7 version 2 HL7 version 3	Health Level Seven www.hl7.org
	DICOM (Digital Imaging and Communications in Medicine)	National Electronic Manufacturers Association www.nema.org
Terminologies	International Classification of Diseases-9	World Health Organization www.who.int/en
	SNOMED CT	International Health Terminology Standards Development Organization www.ihtsdo.org
Documents	Continuity of Care Document (CCD)	HL7/ASTM joint project www.HL7.org
Conceptual	HL7 V3 Reference Information Model (RIM)	Health Level Seven www.hl7.org
Applications	Clinical Content Object Workgroup	Health Level Seven www.hl7.org
Architecture	Public Health Information Network	U.S. Centres for Disease Control www.cdc.gov/phn

2.8.3 HL7

Health Level Seven (HL7) is a standards development organization founded in 1987[65]. To date HL7 has created the most extensively used standards for healthcare interoperability. HL7 standard specifies messages for the exchange of key clinical and administrative information and supports a large number of Medical Coding standards like SNOMED-CT, PACS etc. catering for the needs of individual services. Its name is derived from the seventh level of the ISO's Open Systems Interconnect (OSI) model: the application layer. The application layer directs the communication of the end user with the software applications. The primary standards produced by HL7 are adopted for systems integration and interoperability. These standards are listed below:

- 1. HL7 version 2:** HL7 version 2, (version 2x) is a message based specification divided into segments. Each of these segments provides support for electronic messages for administrative, financial and clinical processes [66]. For example, to carry information for Patient Administration, HL7 v. 2.3.1 specifies messages ADT, For General Order HL7 (v2.3.1) specifies message ORM.

An example message from HL7 version 2.3.1, for Patient Admission **ADT^A01** is shown in Figure 4.

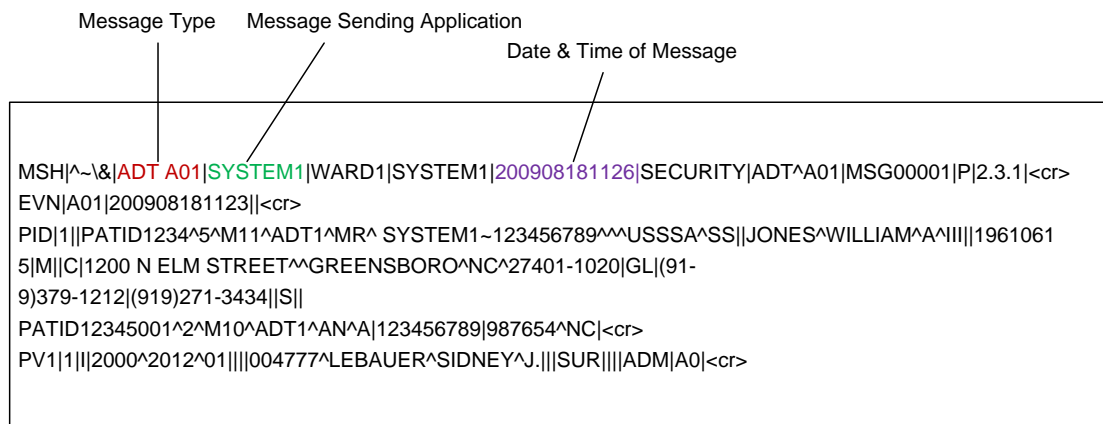


Figure 4: HL7 version 2.3.1 ADT Message

- 2. HL7 version 3:** Version 3 was introduced with the goal of addressing the relationship between different data elements, formal definition of message types and documenting events such as triggers [67]. The HL7 version 3 messages are defined using XML. The

defining structure of the HL7 v 3 is the Reference Information Model (RIM) based on object oriented principles. The RIM addresses the entire healthcare domain. It specifies messages, documents rules and templates for healthcare information. It is based on six foundation classes. A typical HL7 v3 message is shown in Figure 5.

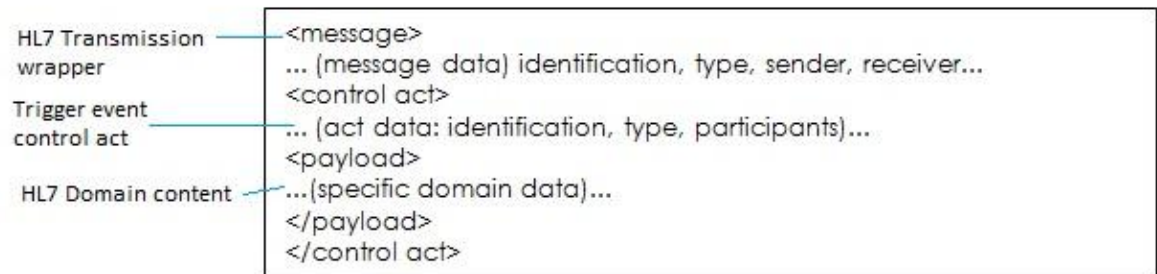


Figure 5: HL7 v 3 message structure

- 3. Clinical Document Architecture (CDA):** Clinical document architecture is an XML-based document exchange standard across healthcare organizations. Based on RIM, a CDA can be both human readable and can also be exchanged by clinical information systems. Examples of CDA include discharge summary, referral, clinical Summary Report [68].
- 4. Continuity of Care Record (CCD):** HL7/ASTM CCD is a joint collaboration between HL7 and ASTM it provides structured document templates for physicians to electronically share patient data without loss of meaning across clinical information systems [69].
- 5. Virtual Medical Record:** The goal of Virtual Medical record standard is “to provide a common information model upon which interoperable clinical decision support e.g. rules can be developed” [70]. Based on the HL7 RIM, the vMR is designed to capture information specifically for clinical decision support. A vMR contains elements like problems and medications or CDS-generated assessments and recommended actions [71].

2.8.4 SOA Standards for Healthcare: Health Services Specification Project (HSSP)

The Healthcare Services Specification Project (HSSP) collaboration between HL7 and Object Management Group (OMG) for developing healthcare standards. The project initiated from the SOA group for HL7 special interest group for Service Oriented Architecture. The focus of this group is to develop specifications for implementation at the middle layer level of architecture of healthcare systems [72]. It has two main constructs:

- 1. Functional Specification:** Identification of core healthcare functionalities that are to be implemented.
- 2. Technical Specifications:** Identification of how the technical capabilities are implemented so as to reach the desired outcome.

Specifications have been developed for SOA based services include: Functional Specification services include: the Decision Support Service; the Entity Identification Service; the Clinical Research Filtered Query Service; and the Retrieve, Locate, and Update Service.

2.9 Research Areas for application of SOA based CDS

2.9.1 Diagnosis and Early Intervention

Diagnosis is an integral functionality provided by Clinical Decision support. By embedding the knowledge engrained in evidence based clinical guidelines in a CDS knowledge base, the aim of providing diagnosis based on current scientific evidence can be fulfilled. Secondly, CDS if provided at the appropriate times, can benefit the physician to start early interventions in serious medical conditions like cancer [73] [74].

2.9.2 Genetic Data guided CDS

Genetic data of the patient when making clinical decisions is not commonly available in the existing EHRs. By providing a rule based CDS intervention for checking genetic data, the effectiveness of CDS can be enhanced. This is in addition to using data input like patient demographics and reported problems [75].

2.9.3 Collaborative healthcare management

Business process management provides support for business and administrative process of an organization by including human interactions with the automated business processes [76]. An example of such a system is Emergency care management in hospitals. Workflows in which humans are actively involved and interact with information systems are called “human interaction workflows” [77]. One of the standards developed to implement such workflows is WS-Human Task Specification [78].

2.10 Research Methodology-Design Science Research

For this thesis, the research methodology Design Science Research Methodology (DSRM) is used. Design Science Research Methodology (DSRM) has been adopted as a research method in both Engineering and Information Systems disciplines. It provides a practical research model for the producing “artifacts to resolve real-world problems” [79]. Hevner [80] has defined DSRM as follows:

“Design science research is a research paradigm in which a designer answers questions relevant to human problems via the creation of innovative artifacts, thereby contributing new knowledge to the body of scientific evidence. The designed artifacts are both useful and fundamental in understanding that problem.”

In the context of healthcare IT, the design of an IT system must provide a solution to the real time problems for the healthcare professionals. Since the focus of this thesis is on the design and architecture of CDS systems, this methodology is used to guide the various steps of the research. The following steps of the DSRM are mapped to the results of the review and research questions:

1. Problem identification and motivation: This includes

- Identify challenges such as interoperability among healthcare IT components that together provide CDS functionality.
- Dissemination of best practices for CDS

2. Define the objectives for a solution:

- Integration of CDS knowledge base with EHRs based on Service Oriented Architecture principles.
- Provide CDS recommendations and alerts to the physician at the point of care.

3. Design and development.

- Model the selected clinical guidelines using graphical modelling tools such as BPMN
- Define CDS knowledge base using rule-based approach
- Deploy the executable guidelines in a runtime environment

4. Demonstration.

- Example case studies for COPD, Lung Cancer, Newborn screening for Cystic Fibrosis and emergency resources' management.

5. Evaluation.

- Evaluate the CDS service against standardised evaluation criteria.

2.11 Implementation Strategy

For implementation of this research, the following two strategies have been considered:

2.11.1 Minimum Viable Product

“A minimum viable product (MVP) is a development technique in which a new product or website is developed with sufficient features to satisfy early adopters. The final, complete set of features is only designed and developed after considering feedback from the product's initial users.”[81]

For the purpose of this research, a prototype CDS is developed, which is then evaluated using multiple case studies. The guidelines implemented as test scenarios are tested against the key priorities for implementation which are defined for individual guidelines. The idea is to confirm the feasibility of the proposed framework with these requirements, which would indicate the use of this research for more complex guidelines.

2.11.2 Agile Software Development

The software development methodology, Agile software development [82] is selected for its cyclical approach with the goal of continuous improvement. The Agile Software Development Manifesto is listed below:

1. Individuals and interactions over processes and tools
2. Working software over comprehensive documentation
3. Customer collaboration over contract negotiation
4. Responding to change over following a plan

The agile software development approach captures software requirements at a high level (light and visual). A pre-requisite of the agile development methodology is that a collaborative and cooperative approach between all stakeholders is essential.

2.12 Results and Discussion

The literature review conducted for this chapter has resulted into the following findings:

1. Clinical decision support is a fundamental agent to support healthcare IT efforts to improve clinical outcomes.
2. The use of CDS is more likely to be practiced if provided as a part of the clinical workflow.
3. To avoid complexity while designing such a system, the guidelines based decision rules need to be separated from the actual EHR or CDSs.
4. A Clinical Guideline is a stepwise sequence of directions for a physician to follow during a care delivery process. This sequence of steps can be modelled using BPM techniques.
5. Service oriented architecture can serve as the architectural foundation for implementing healthcare information systems such as CDS systems.
6. The pillars of realizing the promise of CDS [5] include the use of best knowledge when available. Evidence based clinical guidelines are one mechanism to achieve this goal.
7. Standards based design and implementation of a CDS service can promote interoperability across multiple settings that access these services.

8. By adopting a methodology such as Design Science Research, a formal approach towards design and implementation of a CDS service can be adopted.

2.13 Conclusion

From the literature survey for SOA based design and implementation of CDS, it can be concluded that there is a need for a framework that encompasses all the necessary components to provide CDS at the point of care. Such a framework should include interface components, integration components, CDS service and clinical knowledge base. By integrating these components in a service oriented manner, the primary challenge of interoperability can be overcome. This research will focus on the challenge of “**Creating an architecture for sharing executable CDS modules and services**” that facilitates modelling clinical guidelines and executing them as a part of clinical workflow to enable clinical decision support.

Part II: Architecture Design and Implementation

Chapter 3 Guideline Representation and Execution Model

Tools, Technologies and Development of the CDS Framework

Chapter 3

Guideline Representation and Execution Model: Tools, Technologies and Development of the CDS Framework

Chapter 3

GUIDELINE REPRESENTATION AND EXECUTION MODEL: TOOLS, TECHNOLOGIES AND DEVELOPMENT OF THE CDS FRAMEWORK

“It is only through enforced standardization of methods, enforced adoption of the best implements that faster work can be assured.”

-F.W Taylor

3.1 Introduction

This chapter introduces the CDS Framework which is a service oriented architecture solution that implements evidence-based clinical practice guidelines to enable patient specific decision support for the physician at the point of care. The tools, technologies and techniques that are utilized to put together the CDS Framework are explained in detail. The implementation process for the development of web-service based components that constitute the CDS Framework is presented. This is a standards based architecture solution leveraging HL7/OMG Decision Support Service and HL7 Virtual Medical Record. The clinical knowledge embedded in the clinical guidelines is represented using BPM techniques and executed using SOA best practices. The applications of this framework are clinical and organizational case studies, presented in Chapters 4, 5 and 6.

3.2 Chapter Organization

The chapter is organized as follows. Section 3.3 presents an introduction to the CDS Framework. 3.4 describes the Standards Implemented for the CDS Framework. The system design is described in section 3.5. The components that build up the framework are presented in section 3.6. Section 3.7 presents the CDS Framework deployment specifications. 3.8 describes results and finally 3.9 presents the conclusion.

3.3 Introduction to the CDS Framework

“CDS Framework” is the name given to a collection of components that together provide an architecture capable of implementing clinical guidelines for decision support. Combining Business Process management and SOA concepts, it is built on agile development principles to create flexible and robust business processes. Since the focus of this thesis is in healthcare business processes, the term ‘*business process*’ is used to describe the clinical and non-clinical processes in a healthcare setting.

3.4 Standards Implemented for the CDS Framework

The CDS Framework has leveraged two standards for CDS functionality

1. **For Standard Interface:** HL7/OMG Decision Support Service Standard⁶
2. **For Standard Data Models:** HL7 Virtual Medical Record (vMR) Standard⁷

3.4.1 HL7-OMG Decision Support Service (DSS)

The HL7 Decision Support Service standard was initiated in 2005 as part of HL7/OMG Health Service Specification Project (HSSP) [83]. The aim of developing this standard was to provide an interface specification of a decision support service. “A decision support service provides machine-interpretable, patient-specific assessments and recommendations based on the input data”. Hence resulting into a collective set of functionality that is executed by a decision engine. The need for this standard arose when data used for clinical

⁶ <http://hssp-dss.wikispaces.com>

⁷ [http://wiki.hl7.org/index.php?title= Virtual_Medical_Record_\(vMR\)](http://wiki.hl7.org/index.php?title=Virtual_Medical_Record_(vMR))

decision support was extracted from multiple data sources and there was no mechanism to communicate this data in a structured format that would be compatible amongst multiple applications. One of the key features of this standard is that it was specifically designed to support Service Oriented Architecture based implementation in healthcare IT.

A DSS is used by a DSS Client, which is an external application or systems that utilizes the DSS to obtain the CDS service from the DSS. The client application submits relevant patient data and specifies which knowledge module is to be utilized to obtain patient evaluation. As a response the DSS provides the patient inference in a structured format. A high level DSS architecture is presented in Figure 6. An example scenario can be providing patient age and symptoms as an input, and an evaluation output can be a diagnosis for a particular disease from the DSS. For making this patient evaluation, the following four pieces of information are communicated between the DSS and Client application:

1. Evaluate Patient:

DSS Client: Required patient data and knowledge modules to use

DSS: Patient specific assessment results

2. Find Knowledge Modules:

DSS Client: Search criteria for relevant knowledge modules

DSS: Resulting knowledge modules that meet the search criteria

3. Get Data Requirements:

DSS Client: What data is required as a result?

DSS: Present data results as requested

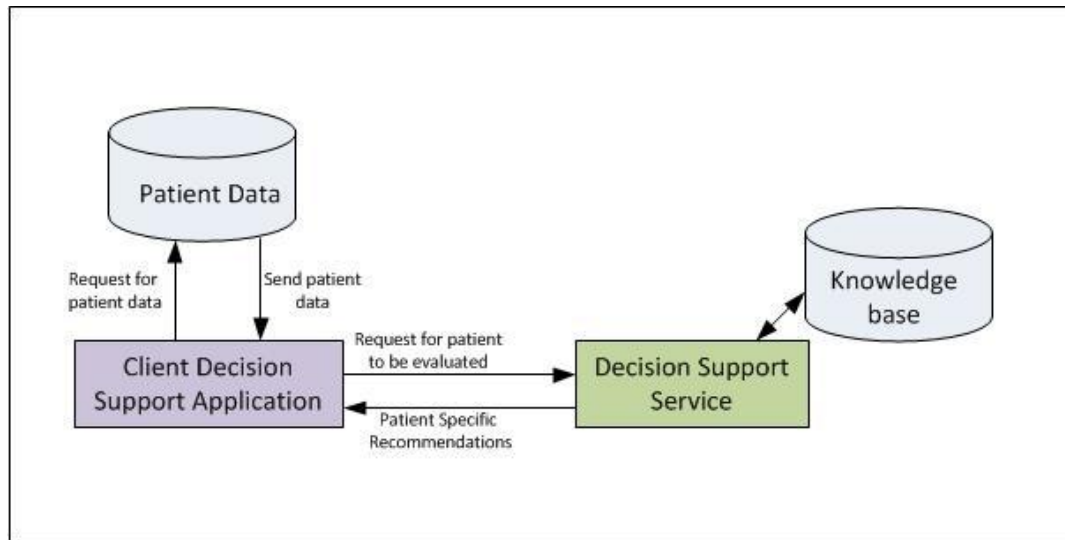


Figure 6 DSS Architecture Overview

3.4.2 HL7 Virtual Medical Record (vMR)

Virtual Medical Record (vMR) is a data model that is specifically developed to represent clinical data for the purpose of clinical decision support [84] [85]. The aim of developing a CDS- specific data model is to simplify the complex clinical data that is difficult to understand by a knowledge engineer who is designing the CDS functionality. Secondly, it aims to provide a common information model to develop interoperable CDS resources (e.g. rules). The vMR consists of data elements like patient demographics, clinical history, and CDS inferences for the patient (i.e. patient-specific recommendations). vMR is based on the HL7 version 3 data types. Important constructs of the vMR are listed below:

1. Logical Model:

- **vMR:** This file contains the data about the patient relevant for CDS
- **cdsInput:** This file specifies the input data used by a CDS system
- **cdsOutput:** This file specifies the output data generated by the CDS system.

2. vMR Payload:

The vMR payload is the data structure that is used to carry the information for CDS Input and CDS Output. Some of the key elements of vMR Payload are:

- **Person:** Patient Name, address and telecom

- **Evaluated Person** : Patient demographics like gender, birth time etc.
- **Clinical Statement**: Clinical statement records an event of clinical nature like observations, problems and procedure.

The Class diagram for a vMR is shown in Figure 7.

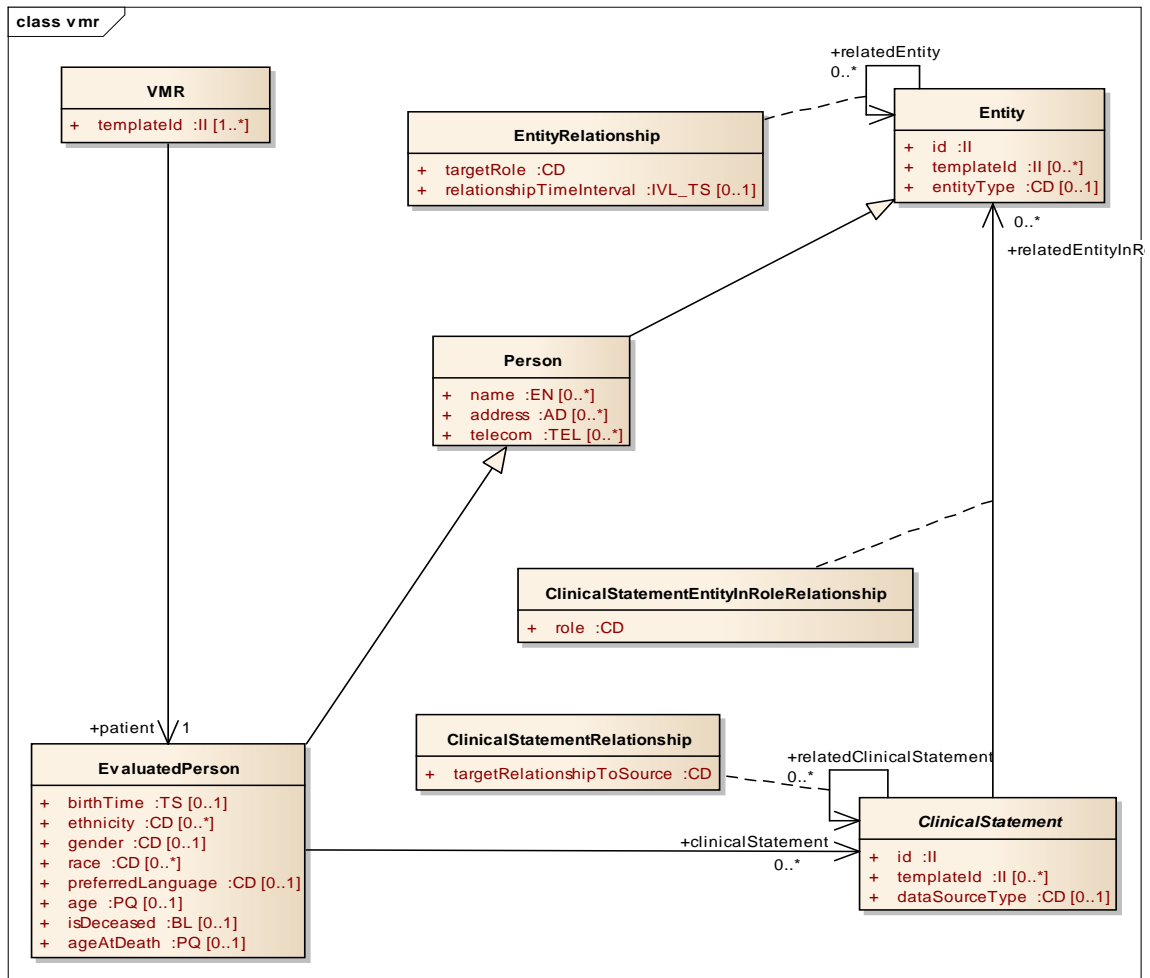


Figure 7 vMR Class Diagram

3.5 System Design

The CDS Framework is designed using the design principles for a CDSS [86] system.

3.5.1 Clinical data representation:

The Medical knowledge is represented using the HL7 vMR standard. The vMR standard requires that, the data to be exchanged among applications providing CDS functionality must be in compliance with the vMR data model. vMR data model supports a common information model that can be exchanged amongst interoperable CDS implementations. This also includes the codes, classifications, and vocabularies. For each element representing clinical data vMR necessitates specifying the code system. This is particularly helpful for data exchange across source and destination applications.

3.5.2 Reasoning:

For the implementation of the CDS Framework, Rule-Based reasoning is adopted. Rule-based reasoning works on the principle of providing an outcome based on the meeting of certain criteria. These criteria are represented in the form of rules. The CDS functionality provides a result based on the matching of evaluation logic with the knowledge contained in the knowledge modules. The basis of rule based reasoning is IF-THEN inferences. Rule-based reasoning is provided by Drools rules engine which is based on the Rete's algorithm. The Rete algorithm is a pattern matching algorithm for implementing rule systems. Its function is to decide which rule to fire when compared to its existing knowledge store and then progressing to the next rule.

3.5.3 Knowledge Acquisition:

For knowledge acquisition, the primary issue is knowledge engineering. Knowledge engineering refers to the process of building a knowledge base. For the CDS Framework, the knowledge engineering process consists of the following steps:

1. Acquiring domain specific knowledge. This entails identifying clinical scenarios that are to be implemented using the CDS Framework. Clinical practice guidelines that represent the sequential steps of the clinical workflow are selected.
2. The selected clinical guidelines are decomposed into logic items or rules.
3. Each rule is then represented as a task.
4. A workflow is modelled representing the sequence of execution of each task.

5. The collection of these tasks results in a business process that represents the clinical workflow as specified by the clinical guideline.

3.5.4 Human Computer Interaction:

The issue of managing human-computer interfacing is addressed by using a standards based interface for the end user. This is provided by the Tolven eCHR™ application that was carefully designed to meet a physician's requirement when having a patient encounter.

3.5.5 SOA Design Principles

The SOA design principles that need to be considered for a SOA based CDS are listed below:

1. **Business Oriented:** Reflecting the business functionality in the services
2. **Granularity:** Granularity refers to the number of services in the SOA based solution and also the scope of each service
3. **Loose-coupling:** As the core objective of SOA is high degree of independence among the services, so a mechanism to maintain minimal amount of state information is favourable.

3.6 System Implementation Components

To design and implement the business processes based on SOA and BPM principles, the CDS Framework constructs are divided into the following parts

1. User Interface Component
2. Process Modelling
3. Process execution
4. Integration (On premise and On Cloud)
5. Communication

3.6.1 User Interface Component: Tolven Electronic Health Record Application

Tolven is an open source EHR platform. It is certified by the Office of the National Coordinator (ONC) for Meaningful Use provider of healthcare IT services. The Tolven electronic Clinician Health Record eCHR™ is a web based application supporting the basic clinical processes and allows healthcare data exchange across third party solutions. Tolven eCHR™ application is selected based upon the following rationale:

1. It incorporates the necessary clinical information to be recorded and saved in the Tolven database.
2. The patient data is encrypted and exchanged over secure connections with other healthcare applications.
3. The user interface is easy to access and use by a physician. The user can modify the view of the clinical data for the patient by adding or removing various elements.
4. Patient data can be transmitted across applications using the structured document Continuity of Care Document. As explained in Chapter 2, CCD is a standard for structured medical utilizing the ASTM's standard Continuity of Care Record (CCR) and HL7 Clinical Document Architecture⁸(CDA). Having the patient summary record in this structured format allows for interoperable exchange of patient data across multiple applications on disparate platforms.
5. Tolven Platform and its applications are licensed as open source hence making it possible to integrate with other healthcare implementations.

3.6.2 Process Modelling using BPMN

Business Process Modelling and Notation is a graphical modelling standard that allows creating process models emulating a real-life business scenario. BPMN is developed by Object Management Group [87]. BPMN is a widely recognised standard for representing real-life business scenarios in enterprises. For a healthcare enterprise, BPMN can be used to visually model a clinical guideline. This model is then transformed into an executable form using Service Component Architecture. A distinct feature of BPMN lies in the fact that it

⁸ HL7/ASTM Continuity of Card Document
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=6

allows non-IT experts to visually create processes. Thus non-technical stakeholders like physicians can actively engage in creating clinical workflows using BPMN. BPMN 2.0 Specification involves different types of diagrams namely Process Diagrams, Collaboration Diagrams and Conversation diagrams. The types of diagrams that will be utilized for the CDS Framework include Process Diagrams (Clinical Guidelines representation in Chapter 4 and Chapter 5) and Collaborative diagrams (Collaborative healthcare management, Chapter 6) BPMN models for the CDS Framework are developed using Eclipse BPMN2 Modeller. This tool is based on Eclipse Graphiti and uses BPMN 2.0 EMF Metamodel. The metamodel is compatible with the BPMN 2.0 Specification developed by the Object Management Group. The detailed description of BPMN Modelling language is presented in Appendix 2.

3.6.3 Process Execution (CDS Processing)

For CDS process execution, the following tools are used:

3.6.3.1 Java Plugin for Tolven eCHR™

In order to communicate the clinical data recorded in Tolven eCHR™ for the purpose of CDS, there is a need to develop an interface application between these two components. From an architectural point of view, the Tolven platform is composed of the following components:

- 1. Browser:** a web browser is used as a means to provide user interaction.
- 2. Web Server:** This component uses Java Server Faces to generate web pages
- 3. Application Server:** The application server is built using Enterprise Java Beans framework. It manages service requests from web server and external applications.
- 4. Database:** PostgreSQL is used as the database for storing application data.
- 5. Extensibility specification:** This specification provides the extensibility functionality for Tolven. The information is maintained in libraries with methods that define how the Tolven application can be extended to provide additional functionalities by interacting with external application via web service interface or other communication mechanisms.

- 6. LDAP:** The user management feature is provided by Lightweight Directory Access Protocol (LDAP). It facilitates rights, privileges and displaying relevant data for a particular user.

Tolven Architecture Components and underlying technologies are shown in Figure 8.

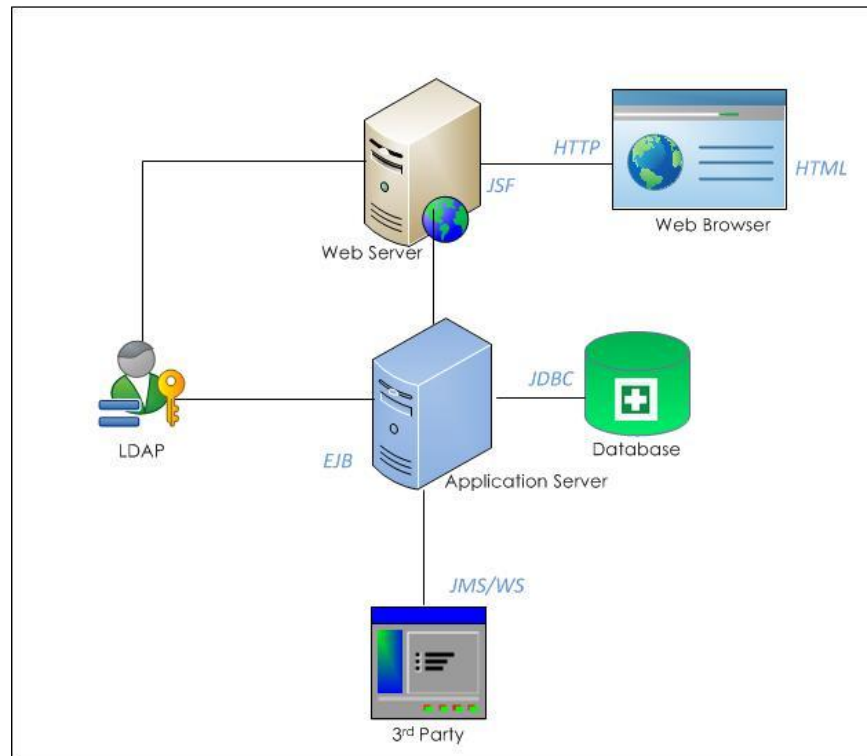


Figure 8 Tolven Architecture Components and underlying technologies

Based on the available components in the Tolven Platform, an interface component is developed using Java EE whose main function is to enable a bridge between external CDS Service and Clinical data that resides in the Tolven database. This application component is named “*TolvenCDSServicePlugin*”. The *TolvenCDSServicePlugin* consists of two parts:

- 1. Cds.drl:** It is a Drools file composed of business rules. The rules relevant to this framework are listed below:

- a. Trigger a business rule as soon as there is a change in the patient data in the Tolven database. For example, physician enters new information into the patient record. Triggering this business rule means an instance of the *Operationbean* is created.
- b. Display the results of the CDS processing obtained from the CDS service to the Tolven eCHRTM Interface. The placement of this resulting information is also specified that is the “Alerts” section.

2. OperationBean: The OperationBean is a Java bean class that consists of a set of invokable operations. It performs the following operations:

- a. Collect patient information from Tolven database
- b. Transform the extracted data into a vMR format
- c. Sending the vMR in a service request to the CDS service.
- d. Receiving the response from the CDS service

Conceptual Diagram for CDS Framework and Tolven Interaction using the plugin is presented in Figure 9.

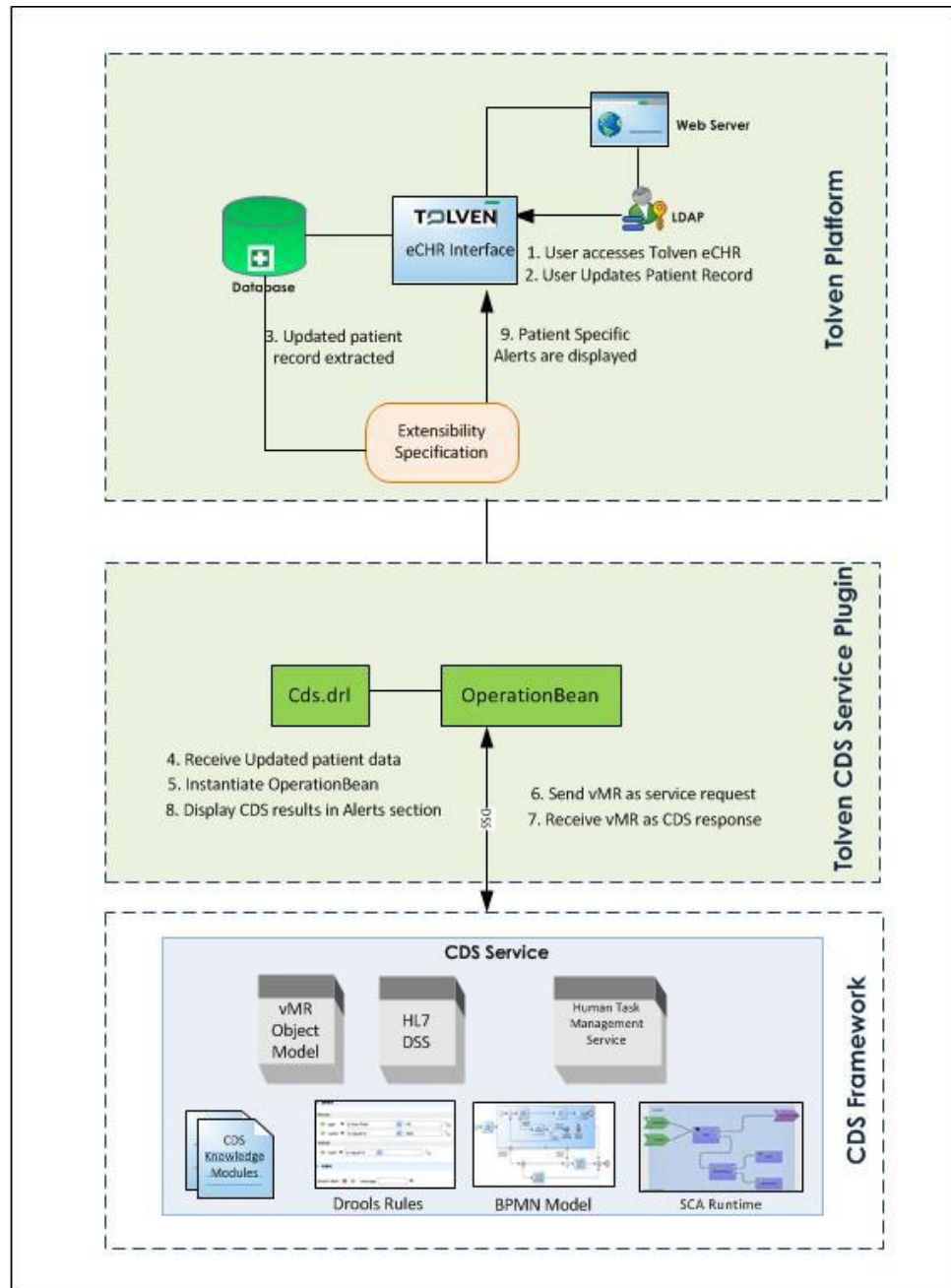


Figure 9 Conceptual Diagram for CDS Framework and Tolven Interaction using the Plugin

3.6.3.2 JBoss Drools

Drools is a business Rules Management System (BRMS), part of the JBoss Enterprise BRMS⁹. This rules engine is selected based on the following rationale:

⁹ <http://docs.jboss.org/drools/release/5.2.0.Final/drools-expert-docs/html/ch01.html>

- 1. Support for Declarative Programming:** In a rule-based structure, Drools Rule engine specifies what action is to be taken when a certain condition is met rather than how to perform that action.
- 2. Separation of Data and Logic:** The clinical data resides in the domain Objects (Java Objects) while the logic of the business process resides in the rules. This allows modifying the business logic in an simplistic manner
- 3. Tool Integration:** As the CDS Framework is built by integrating a number of open source tools and technologies, the JBoss Drools rules engine can integrate tools like Eclipse development environment.

3.6.3.3 jBPM

jBPM is a flexible web based Business Process Management (BPM) Suite¹⁰. The jBPM delivers the following functionality in the CDS Framework:

1. It is a java based workflow engine, allowing process management in addition to a business process authoring environment.
2. Business Processes are executed by using the latest BPMN 2.0 specification.
3. It has artifact repository in which data models such as vMR Virtual Medical Record can be imported and implemented.
4. Allows integrating a Drools project and creates an environment where these tools can be integrated to execute the business logic, rules and events.
5. Supports the WS-Human Task specification for including tasks that are performed by human actors in a business process.

¹⁰ <http://www.jbpm.org/>

3.6.3.4 KIE-Workbench

KIE-Workbench is an open source framework combining both the Drools Rule Engine and jBPM workflow engine functionality. It allows authoring of rule-based projects, test services, process authoring, a process run-time execution environment and human task interaction.¹¹

Since the goal of this thesis is to provide an integration solution for CDS processes, The above tools were exploited to gain an understanding of open source application environments available for building an open source solution. This is particularly important as these frameworks are continually evolving to meet the needs of the enterprise implementation of Business Processes. The idea is to provide an insight into the use of these technology platforms for the field of healthcare as they are extensively used in other industries.

3.6.4 Integration (*on premise*)

3.6.4.1 Enterprise Service Bus: SwitchYard

For Service Oriented Computing paradigm, one of the most integral parts of the implementation is the Enterprise Service Bus. For CDS Framework, a light-weight enterprise application integration platform SwitchYard is used. SwitchYard is a “lightweight service delivery framework providing full lifecycle support for developing, deploying, and managing service-oriented applications”¹².

For the CDS Framework SwitchYard provides the following functionality:

- 1. Enabling SCA Runtime:** SwitchYard runtime environment consists of components such as composite services and composite references. It allows visualizing components of a SwitchYard application graphically. The SCA runtime is enabled using this environment.
- 2. Content-Based Routing Pattern for enterprise integration:** The content based routing mechanism enabled by the Apache Camel allows routing a message to the destination based on the contents of the message exchanges.

¹¹ <https://github.com/droolsjbpm/kie-wb-distributions/tree/master/kie-wb>

¹² <http://switchyard.jboss.org/>

- 3. Apache CXF Web Services Framework¹³:** The web services framework adopted for the CDS Framework is open source Apache cxf framework. For building services, this standard supports multiple front-end programming APIs. The services built using this framework can communicate across a variety of protocols like SOAP, HTTP and can be transported over mechanisms like HTTP and JMS.
- 4. Enabling Decision Services:** the JBoss Rules component in SwitchYard embeds business rules as decision services. Service Contracts are well defined with protocol binding details and marshalling.
- 5. Transformations:** SwitchYard registers and executes the transformation for Java

3.6.5 Integration (*Cloud based*)

3.6.5.1 Overview of Google Cloud Platform¹⁴:

Google Cloud platform is a collection of cloud computing products from Google. The products for hosting and computing include App Engine and Compute Engine, The Google computer engine is the Infrastructure as Service (IAAS) component that allows users to host various Virtual Machines enabling developers to host and scale applications the cloud. The rationale for selecting this platform for cloud based implementation of the CDS Framework is as follows:

- 1.** Consists of high performing Virtual machine environments with support for Debian and CentOS Linux environments.
- 2.** Consists of integrated development tools and interface that allow for deploying existing applications and components.
- 3.** Supports a wide variety of programming languages including Java EE
- 4.** Automates the process of infrastructure provisioning and administration of resources like memory and speed.
- 5.** Allows managing internal and external network access.
- 6.** Supports various applications built using open source tools and technologies.

¹³ <http://cxf.apache.org/>

¹⁴ <https://cloud.google.com/>

3.6.5.2 CDS Framework Cloud Implementation

The CDS Framework Cloud integration can be described as Software as a Solution. This is a hybrid approach for cloud implementation. A hybrid implementation allows the organization to manage systems like legacy systems and data centres that it needs to keep on premise, as well as by hosting the systems that are more readily required by the customers on the cloud. For the CDS Framework, the as the core functionality components of this framework are exposed as a software in the Google Cloud environment. Following components from the CDS Framework are deployed on the cloud:

1. **CDS Service for Genetic Testing:** The CDS service can be accessed by multiple healthcare institutions that need the functionality for GT enabled CDS
2. **KIE-Workbench:** Business Processes such as clinical guidelines can be implemented using KIE-Workbench environment. This includes rule authoring, user management and process models.

The above components provide the Software as a service approach for cloud implementation.

3.6.6 Communication using SOAP Based Web Services

The web services designed to facilitate the CDS Framework are based on the SOAP (Simple object access protocol) communication protocol. SOAP is a light-weight defines a standard XML-based messaging format for web services communication. SOAP provides independence in terms of communication protocol. It can be used for HTTP and JMS transport protocol. SOAP based web services are founded on the following three constructs:

1. **WSDL:** Web Services Description Language describes the functionality of the web services and specifies the physical location of the service (URL/address). It describes the point of contact for the service provider. WSDL is also called *Service Endpoint*
2. **UDDI:** Universal Description Discovery and Integration is used to categorise and publish available web services in a repository and allow discoverability to service users,

3. SOAP Message: It is an XML document. The mandatory elements are an envelope element (identifies SOAP message as XML), and a required body component (request and response information)

Figure 10 and Figure 11 shows a sample SOAP request and Response message for CDS Framework respectively.

```
<soap:Envelope xmlns:soap="http://www.w3.org/2003/05/soap-envelope" xmlns:dss="http://www.omg.org/spec/CDS/201105/dss">
  <soap:Header/>
  <soap:Body>
    <dss:evaluateAtSpecifiedTime>
      <interactionId scopingEntityId="edu.utah" interactionId="123456" submissionTime="2012-01-11T00:00:00.000"/>
      <specifiedTime>2011-01-01T00:00:00.000</specifiedTime>
      <evaluationRequest clientLanguage="?" clientTimeZoneOffset="?">
        <!--1 or more repetitions-->
        <kmEvaluationRequest>
          <kmId scopingEntityId="org.opencds" businessId="WGS_v1" version="latest"/>
        </kmEvaluationRequest>
        <!--1 or more repetitions-->
        <dataRequirementItemData>
          <drId itemId="payload001">
            <containingEntityId scopingEntityId="edu.utah" businessId="NQFData" version="1.0.0"/>
          </drId>
          <data>
            <informationModelSSID scopingEntityId="org.opencds.vmr" businessId="VMR" version="1.0"/>
            <base64EncodedPayload>PD94bWwgdGVyc2lvcj0iMS4wIiB1bmNvZGluz0iVVRGLTgiPz4jwHLS1TYW1wbGUGwE1MIGZpbGUGZ2Vv
          </data>
          </dataRequirementItemData>
        </evaluationRequest>
      </dss:evaluateAtSpecifiedTime>
    </soap:Body>
  </soap:Envelope>
```

Figure 10 SOAP Request

```
<soap:Envelope xmlns:soap="http://www.w3.org/2003/05/soap-envelope">
  <soap:Body>
    <ns2:evaluateAtSpecifiedTimeResponse xmlns:ns2="http://www.omg.org/spec/CDS/201105/dss">
      <evaluationResponse>
        <finalKMEvaluationResponse>
          <kmId scopingEntityId="org.opencds" businessId="WGS_v1" version="latest"/>
          <kmEvaluationResultData>
            <evaluationResultId itemId="payload001.EvaluationResult">
              <containingEntityId scopingEntityId="edu.utah" businessId="NQFData" version="1.0.0"/>
            </evaluationResultId>
            <data>
              <informationModelSSID scopingEntityId="org.opencds.vmr" businessId="VMR" version="1.0"/>
              <base64EncodedPayload>PD94bWwgdGVyc2lvcj0iMS4wIiB1bmNvZGluz0iVVRGLTgiPz4jwHLS1TYW1wbGUGwE1MIGZpbGUGZ2Vv
            </data>
            </kmEvaluationResultData>
          </finalKMEvaluationResponse>
        </evaluationResponse>
      </ns2:evaluateAtSpecifiedTimeResponse>
    </soap:Body>
  </soap:Envelope>
```

Figure 11 SOAP Response

3.7 Framework Deployment

3.7.1 Development Environment

The framework components and their respective hardware and software development environment is shown in Table 6

Table 6 Development Environment specifications for CDS Framework

Framework Component	Hardware	System Software	Operating System
Tolven EHR			
Tolven eCHR™ Web Application 1. PostgreSQL 2. JBoss Application Server 6 3. Directory Service OpenDS 4. Rule Engine Drools	X64 Machine	Oracle JVM 1.6	Linux CentOS version 5.8
Enterprise Service Bus SwitchYard			
JBoss SwitchYard ESB 1. Drools Rule Engine 2. JBoss jBPM 3. Apache Camel	x64 machine	Oracle JVM 1.7	Linux Ubuntu Server version 12.04 LTS
Eclipse IDE			
	x64 machine	Oracle JVM 1.7	Linux Ubuntu Server version 12.04 LTS
JBoss jBPM Console (KIE Workbench)			
JBoss jBPM Engine and Web Interface	x64 machine	Oracle JVM 1.7	Linux Ubuntu Server version 12.04 LTS

3.8 Evaluation of the CDS Framework

3.8.1 CDS Service Evaluation:

The CDS Service Evaluation of the CDS Framework is based on load testing of the CDS Service. This includes measuring the request and response time. Given the hardware limitations for testing this prototype, simultaneous requests from a relatively small healthcare settings for a maximum of 60 users are evaluated. The response time is evaluated against the standard for efficient CDS Service i.e. sub-second response. Sub-

second response time the standard for efficient CDS [88]. If the response takes less than a second, it is considered to be a success criteria for the feasibility of this solution.

3.8.2 Architecture Evaluation

Based on the Evaluation of SOA provided by Pianco et.al [89] and SEI, [90], the architecture evaluation involves the following criteria

- 1. Modifiability:** The clinical practice guidelines that are represented using BPMN Processes allow modifications.
- 2. Performance:** User submits data to the application and receives a response from the CDS Service
- 3. Reliability:** The CDS Framework provides accurate results in conformance to the clinical practice guidelines that are used for evaluating a clinical case.
- 4. Interoperability:** The CDS Framework allows communication among interoperable components by the use of enterprise service bus.
- 5. Availability:** The CDS Service instantiates as soon as a change in the EHR is recorded.

3.9 Results and Discussion

The integration solution which is a result of combining several open source tools and technologies is the CDS Framework.

The core results achieved from this chapter are listed below:

- 1.** The standards-based implementation (HL7, OMG) ensures interoperability among different healthcare applications.
- 2.** The deployment of this solution involves using the enterprise service bus SwitchYard which allows healthcare data exchange in a simple and robust manner.
- 3.** The reasoning criteria for clinical decision support is based on business rules, which provides a clear representation of these rules using a standardized approach in a BPMN process.
- 4.** The end user interface has been enabled by an open source commercial EHR which is used from the start of the process i.e. entering patient details and receiving the end result of this implementation i.e. alerts and recommendations for patient-specific inferences.

3.10 Conclusion

This chapter has provided a detailed description of the CDS Framework design, development and integration. The purpose of this Framework is to enable SOA based Clinical decision support at the point of care. Leveraging the best practices of SOA, Service Component Architecture is employed to facilitate a web services enabled implementation. This CDS Framework is tested for validation and feasibility in the following chapters employing clinical practice guidelines for clinical, organizational and genetic testing enabled decision support.

Part III: Implementation Case Studies in Healthcare

Chapter 4 *Testing and Evaluation of CDS Framework-Case Studies for Implementation of Clinical Guidelines (Clinical Practice)*

Chapter 5 *Testing and Evaluation of CDS Framework-Case Study for Enabling Genetic Data for CDS At The Point Of Care (Genetic Testing Implementation)*

Chapter 6 *Testing and Evaluation of CDS Framework-Case Study for Collaborative Healthcare Management (Organizational Practice)*

Chapter 4

Testing and Evaluation of CDS Framework-
Case Studies for Implementation of Clinical
Guidelines (Clinical Practice)

Chapter 4

TESTING AND EVALUATION OF CDS FRAMEWORK-CASE STUDIES FOR IMPLEMENTATION OF CLINICAL GUIDELINES (Clinical Practice)

“Diagnosis is not the end, but the beginning of practice.”

— Martin H. Fischer

4.1 Introduction

To improve clinical outcome, there is a need to provide guidelines based Clinical Decision Support for physicians using different EHRs. To avoid complexity while designing such a system, the guidelines based decision rules need to be separated from the actual EHR or CDSs. By taking advantage of the potential of BPM and workflow technology in healthcare, it is proposed that using a workflow management system (WfMS) as a tool to automate clinical guidelines can be a novel approach for enabling CDS in a healthcare setting. To achieve this goal, the functionality needs to be distributed amongst various components participating in the healthcare workflow in order to allow maximum independence between the technologies thus enabling interoperability among EHR environments implemented using different software. Chapter 3 has provided the design and development of the CDS Framework. In this chapter, the CDS Framework is tested to provide output for clinical practice. There are two case studies in clinical practice that are implementing clinical guidelines using the CDS Framework. The clinical workflows of diagnosis of two health conditions have been identified, both of which when automated,

have the potential to markedly improve the clinical practice by incorporating CDS functionality in terms of early intervention. The CDS functionality is visible in the Electronic Health Record interface available to the physician in the form of alerts to take appropriate actions. The guidelines for two conditions namely Chronic Obstructive Pulmonary disease and Lung Cancer published by the National Institute of Health and Care Excellence, UK are used. The initial conditions are checked by the SOA based web services and recommendations are provided to the physicians before proceeding to further steps. The guidelines are represented using BPMN modelling techniques and executed as web services using the Service Component Architecture. The Service results are displayed in the Tolven eCHR™ interface. The service request and response are evaluated using load testing. The aim of the service is to meet the criteria for an efficient CDS Service that provides results in less than a second.

4.2 Chapter Organization

The remaining sections of the chapter are organized as follows: Section 4.3 presents the first Case Study implementation of the CDS Framework that is Diagnosis of Chronic Obstructive Pulmonary Disease. Section 4.4 explains the second case study implementation for the CDS framework that is Diagnosis of Lung Cancer. Section 4.5 provides a discussion of the results of both the case studies. Performance evaluation of the CDS Service is discussed in detail in Section 4.6. The chapter is concluded in Section 4.7.

4.3 Case Study 1: Chronic Obstructive Pulmonary Disease:

4.3.1 Introduction to COPD

Chronic Obstructive Pulmonary disease is a progressive and long-term disease that is characterized by airflow obstruction. An estimated 3 million people in the UK have COPD¹⁵ and 12.7 million in the U.S, it is the third leading cause of death¹⁶. One of the primary causes of COPD is smoking. In rare cases COPD is caused by fumes, dust and air

¹⁵ UK Healthcare Commission (2006)

¹⁶ Centers for Disease Control and Prevention. National Center for Health Statistics. National Vital Statistics Report. Deaths: Final Data for 2010. May 2013; 61(04).

pollution causing inflammation in the lungs and causing them permanent damage. People with COPD have trouble breathing because of obstructed airways caused by irritation and inflammation of the airway passage walls. Over the past two decades the prevalence of COPD has increased with smoking as a primary cause. [91]

4.3.2 Current Challenges with COPD Diagnosis

Out of an estimated 3 million people in the UK, 2 million have COPD which remains undiagnosed. The primary reason for this is that many people who develop COPD do not seek medical help by often ignore their symptoms as a “smoker’s cough”¹⁷. An early diagnosis of COPD is therefore critical in order to decelerate the deterioration of the lungs. A patient presenting with typical symptoms of chronic cough must be checked if these symptoms are in line with a possibility of a COPD diagnosis, especially if the patient is a smoker. This would lead to an early diagnosis thus initiating a treatment process for the patient and reducing chances of further harm to the patient’s health. In order to this achieve goal, the electronic health record application functionality, which is in use by the diagnosing physician must be able to perform the following functions:

1. Facilitate the automation of the latest evidence-based guideline for diagnosis and treatment of COPD as a routine workflow of the physician at the point of care.
2. Enable computerized decision support to the physician in making an informed choice
3. Provide a list of symptoms that are described in the guideline to choose from.
4. Provide a mandatory smoking assessment of the patient.
5. Alert the physician to consider the diagnosis of COPD
6. Provide guidance on treatment options and create a treatment plan
7. Check for an alternative diagnosis

4.3.3 NICE Guideline for COPD

The National Institute of Health and Care Excellence, UK have published a guideline for diagnosis and treatment of COPD. The latest version was published in 2010 [92], which is also the current version being implemented in medical practice for diagnosing COPD in the

¹⁷ NHS Choices-Conditions: COPD

NHS setting. This guideline is also expressed by a care pathway, (an algorithm) which is a step by step guide to diagnosing COPD in the form of a workflow. The workflow representation of the COPD guideline is presented in Figure. 12.

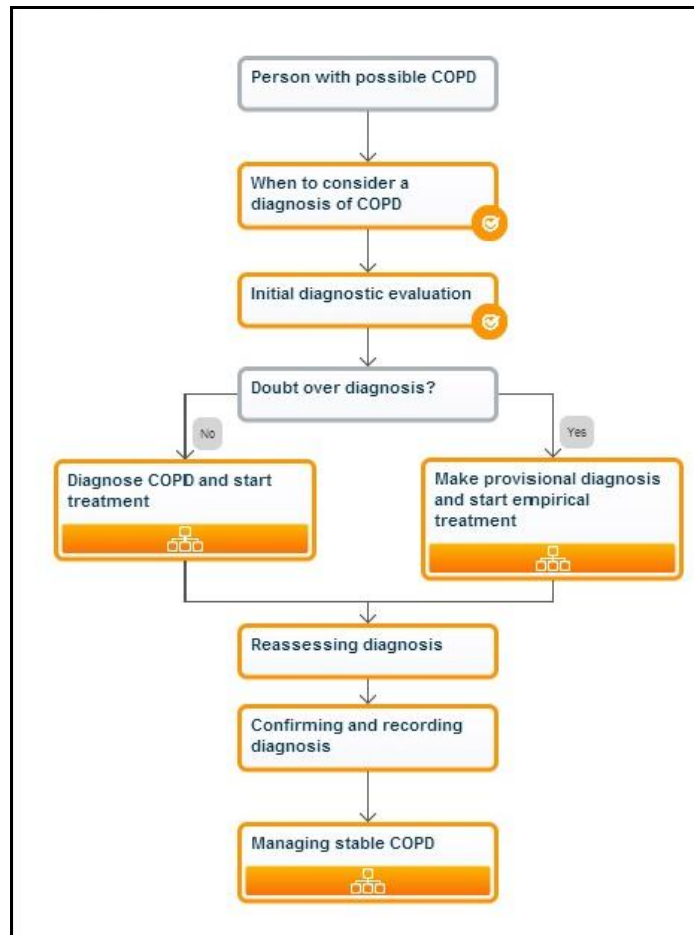


Figure 12 NICE Pathway for COPD Diagnosis and Treatment

This study focuses on the initial stages of diagnosis including “When to Consider a Diagnosis of COPD”. In order to provide CDS to the physician to assist him for making an early diagnosis, the first stages of the pathway are implemented. The conditions for this stage are as follows:

A diagnosis of COPD is considered when patients fit in the following criteria:

1. Age Over 35
2. Smokers and ex-smokers
3. Patient presents with any of these symptoms:
 - a. Exertional breathlessness
 - b. Chronic Cough
 - c. Regular Sputum Production
 - d. Bronchitis
 - e. Wheeze

If the above criteria are met, the physician is required to consider a diagnosis for COPD.

4.3.4 Key priorities for Implementing the COPD Guideline

Using the CDS Framework described in Chapter 3, the above scenario was automated and CDS capability was implemented using Business Process Management techniques and Service Component Architecture principles. In order to take advantage of this architecture solution, the following requirements were identified:

1. The EHR allows recording of the symptoms.
2. The EHR prompts the user to conduct smoking assessment.
3. The diagnosis symptoms expressed in the guideline, if recorded by the EHR are represented graphically to increase visibility and ease of understanding.
4. The guideline is automated as a business process.
5. Symptoms are expressed as business rules.
6. The model is available in an executable form.
7. The model is available as a web service.
8. Clinical decision support is enabled to make a recommendation to the physician.
9. The alerts are displayed to the physician at the point of care using the EHR interface
10. The architecture must be flexible to allow changes to the rules.
11. The CDS functionality meets the criteria for an efficient service

4.3.5 Guideline Representation Model

The COPD Guideline workflow for diagnosis is modelled using BPMN. Each symptom is represented as a task in the process “COPD Diagnosis Consideration”. The BPMN Model represents the following steps.

1. The process starts with checking the age of the patient. If the age of the patient is greater than 35, the process continues to the next step. If that is not true, the process terminates.
2. The next steps involve checking for the symptoms as described in the guideline. If any of these symptoms are present, a smoking assessment is conducted.
3. If the patient is a current or ex-smoker than the last step is reached, which is to consider a diagnosis of COPD.

The Guideline representation model using BPMN is presented in Figure 13

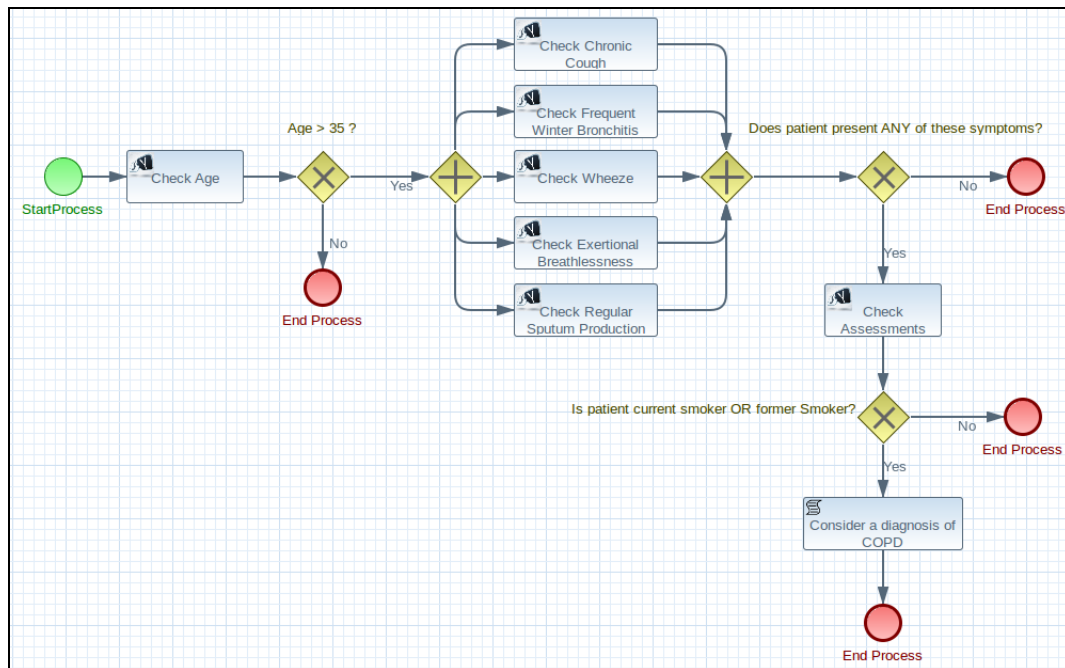


Figure 13 COPD Guideline Representation Model using BPMN

4.3.6 Guideline Execution Model

The following components from the CDS Framework are utilized in the implementation of the COPD Guideline

1. **EHR Application Interface:** The Commercial EHR Tolven is used as a physician's interface for capturing patient data. This is also the interface where an alert will be received by the physician to facilitate clinical decision making.

The screenshot displays the Tolven eCHR™ interface with two main panels. The left panel contains sections for Assessments, Discharge Instructions, Immunizations, and Problems. The right panel contains sections for Medication List, Appointments, Alerts, Reminders, and Encounters.

Assessments				Request		Document	
02/07/2014	Smoking Assessment	Current every day smoker	ACTIVE				

Discharge Instructions				New	

Immunizations				New	

Problems				Document	
02/07/2014	Chronic cough (finding)		ACTIVE		
02/07/2014	Wheezing (finding)		ACTIVE		
02/07/2014	[D]Shortness of breath (situation)		ACTIVE		

Medication List		Review New	

Appointments		New	

Alerts	
02/07/2014	Consider a diagnosis of COPD

Reminders	

Encounters		New	
02/07/14	Ambulatory		

Figure 14 Diagnosis display in Tolven eCHR™ Interface

A screen shot from, Tolven Interface is shown in Figure. 14. The Smoking Assessment is presented in the “Assessments” section. The Symptoms recorded for the patient are presented in the “Problems” section. The result of the CDS functionality is displayed in the “Alerts” section.

2. **Business Rules:** Each problem or symptom recorded by the Tolven eCHR™ is expressed as a business rule. For example the rule for checking age is shown in Figure 15.

```

package uk.ac.sussex.switchyard.switchyard_copd
import org.switchyard.Message
import cdsinput.schema.v1_0.vmr.opencds.org.CDSInput

global Message message
global java.util.Map globals

rule "CheckAge"
  when
    CDSInput(vmrInput.patient.demographics.age.value >= 35)
  then
    globals.put("Result", Boolean.TRUE);
end

```

Figure 15 Business Rule for Checking Age of the patient using Drools

3. **Integration Framework:** The enterprise service bus SwitchYard is used. SwitchYard is a “component-based development framework for building structured, maintainable services and applications based on the best practices of SOA”. jBPM, Drools and Apache Camel are accessed from within the ESB in order to keep our rules functionality easily accessible by EHRs.
4. **Logic Integration Platform:** JBoss Drools is a java based open-source business logic integration platform based upon the RETE’s algorithm.
5. **Workflow Engine:** jBPM is a java based workflow engine that allows for the execution of a business process using the BPMN 2.0 specification.
6. **Message Transformation:** Apache Camel is an open-source integration framework, which functions as a message transformation service. It is a communication mechanism for routing rule-based functions.
7. **Runtime Environment:** SCA Runtime is the Service Component Architecture specification supported by the ESB SwitchYard.

4.3.7 Implementation Methodology

For implementing this guideline using the CDS Framework, BPM Process lifecycle steps using JBoss JBPM are used [93].

The BPM Process Lifecycle is adopted as a methodology as it facilitates accomplishment of the requirements explained in Section 4.3.4. This methodology consists of the following steps:

1. Identify Business Process Workflow
2. Model Process Visually
3. Develop Runtime Components
4. Deploy runtime engine
5. Instantiate Runtime Instance

The above steps and the corresponding adoption with this particular case study is shown in Figure 16

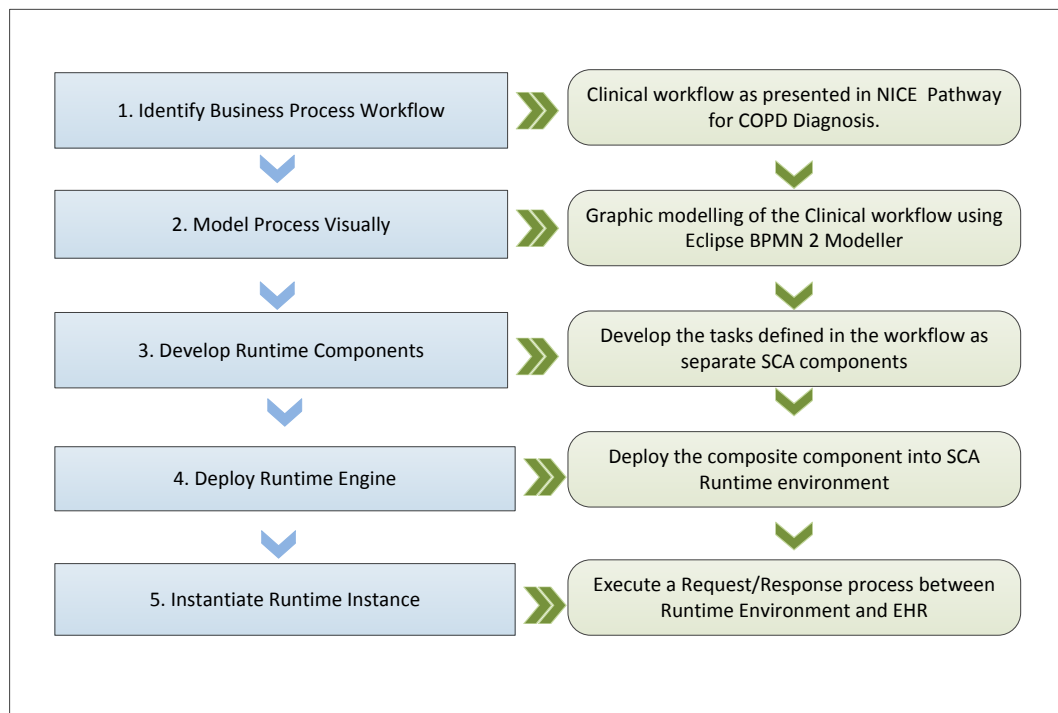


Figure 16 BPM Methodology Steps and Corresponding Case study specific steps

The BPM methodology steps followed for the implementation of COPD case study are explained in detail below:

1. **Identify Business Process Workflow:** The NICE Clinical Pathway as a workflow representing Chronic Obstructive Pulmonary Disease Diagnosis is selected. The rules that govern the completion of each step in the workflow are separated out. These are decision rules e.g. checking a patient's age, problems and smoking assessment as explained in Section 4.3.3.
2. **Model Process Visually:** A graphic model of the clinical workflow identified in step 1 is created. This is done using Eclipse BPMN 2 Modeller. At this stage the rule logic is separated and presented in the tasks. These are separated from the workflow processes, which can later be used by another process.
3. **Develop Runtime Components:** This step involves developing tasks defined in the workflow as SCA Components. Each Task/component (e.g. check age etc) can be wired together into a process "COPD Clinical Guideline"
4. **Deploy runtime Engine:** This stage involves deployment of the composite component into the SCA Runtime environment. The SCA Component Evaluation Service is exposed as a reusable service for the EHR.
5. **Instantiate Runtime Instance:** This step instantiates the process of executing request and response between Runtime Environment and EHR. This is a sequence of four steps:
 - a. A request is generated from the EHR to the SCA runtime,-containing the problems list as entered by the physician for an encounter. This is transferred as a SOAP message .Apache camel extracts the Base 64 encoded Payload and transforms it into the vMR format. The vMR is then transformed to java objects that are accessible by the processes (e.g. Check chronic cough, check Wheeze etc)
 - b. If the conditions are met, a request is sent from BPMN to Tolven requesting information for Smoking assessment.
 - c. A response from Tolven is sent to the CDS service, stating if the patient is a current or ex-smoker. d) The assessment result is sent to CDS service e) an alert is shown to the Physician on Tolven to consider diagnosis for COPD.

4.3.8 CDS process functionality for COPD Guideline

Using the enterprise service bus SwitchYard, the COPD Composite Service is deployed.

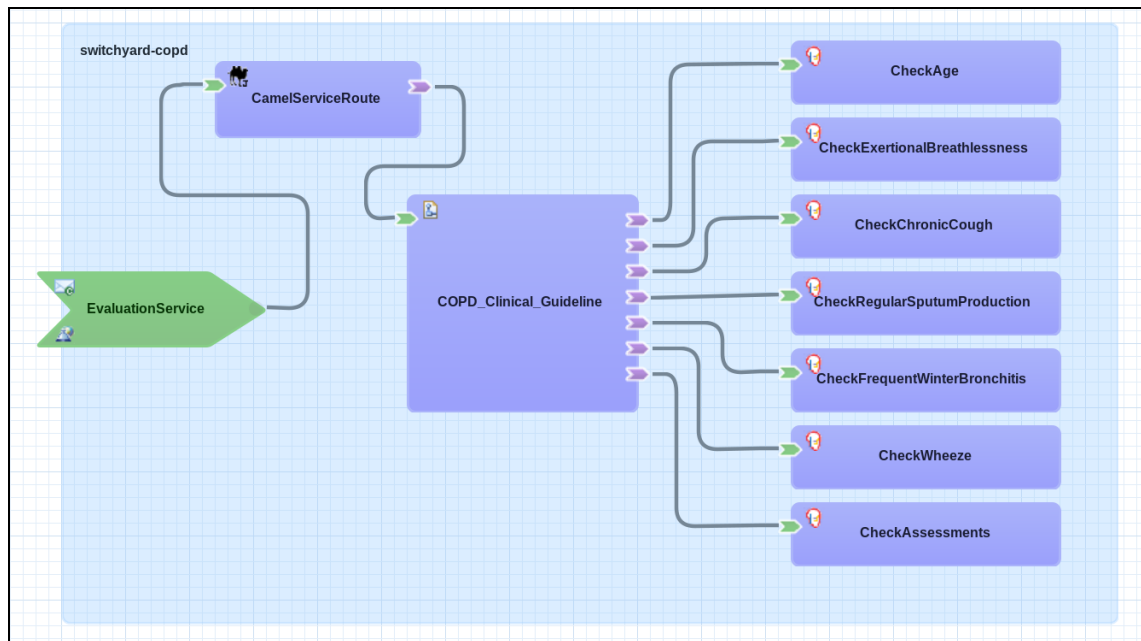


Figure 17 SCA Composite for COPD Guideline Execution

As shown in the Figure 17, the following components are assembled in the SwitchYard deployment environment:

1. **EvaluationService:** The CDS is exposed as SOAP service EvaluationService which is based on the HL7 CDS service standard
2. **CamelServiceRoute:** This component transforms the XML vMR embedded in the SOAP message into a Java object.
3. **COPD_Clinical_Guideline:** This component consists of the various tasks presented in the BPMN model for the COPD guideline. The business process modelled in this component is instantiated when a new Java object is received from the CamelServiceRoute component. The results of the BPMN process are returned as an XML document in the form of a CDS Response.

4. Tolven Plugin: The Tolven plugin is used to transfer the XML response to the Tolven eCHR™ Interface.

4.3.9 Evaluation

The open source load testing software, LoadUI¹⁸ is used, to measure the results of performance testing. The service response times to test the scalability of the service was measured. The service was tested three times for 30, 50 and 60 simultaneous users respectively for a period of five minutes. The results are shown in Table 7.

Table 7 Evaluation testing results for CDS Rules Service for COPD Diagnosis

Time (min)	No of Users	No of Requests	Response Time (ms)
05.00	20	604	293
05.00	40	1202	467
05.00	50	1541	719

The average response time of this CDS service is less than a second with a maximum of 60 users. If the number of simultaneous requests are increased, the response time is likely to increase. For managing a relatively small number of requests, this service is suited for integration within an EHR for a small to medium sized healthcare setting. Detailed test results are provided in Appendix 1.

¹⁸ <http://www.loadui.org/>

4.4 Case Study 2: Lung Cancer

4.4.1 Lung Cancer Introduction

Lung Cancer was the second leading cause of death in 2012 in the UK¹⁹. In the US, it is the second most common type of cancer among males and females.²⁰ In the early stages of Lung Cancer there are no obvious symptoms. However, these symptoms worsen as the disease develops over a period of time. It is generally more prevalent in older people. However in recent times, the younger generation is becoming susceptible to this type of cancer. Smoking is one of the leading cause of Lung Cancer.

4.4.2 Importance of Early Diagnosis

The poor prognosis of early lung cancer 15% survival rate after five years of diagnosis, is due to unavailability of measures to support early detection [94]. Early diagnosis can help control the retract tumour and initiate other therapeutic measures like chemotherapy for the patients. Some early signs and symptoms for detecting this condition exist, that if prompted to the physician at the appropriate time, can improve the process of diagnosis [95]. There is a need to facilitate the physician in a patient encounter to record the symptoms in an EHR and the EHR with its CDS capability can provide quick recommendations to the physician to support their diagnostics and treatment options. The diagnosis of lung cancer can be confused with other conditions like COPD, Bronchitis and Pulmonary Tuberculosis [96].

4.4.3 NICE Guideline for Lung Cancer

The NICE UK's Guideline "The diagnosis and treatment of Lung Cancer" (CG121) has been selected for this case study [97]. The guideline provides a sequence of actions that need to be performed by the physician in order to consider a diagnosis for Lung Cancer. For early intervention, if the initial symptoms are met, an immediate referral and order for Chest X-Ray is made as shown in Figure 18.

¹⁹ ONS: Part of Mortality Statistics: Deaths Registered in England and Wales (Series DR), 2012 Release <http://www.ons.gov.uk/ons/rel/vsob1/mortality-statistics--deaths-registered-in-england-and-wales--series-dr-/2012/sty-causes-of-death.html>

²⁰ U.S. Cancer Statistics Working Group, United States Cancer Statistics: 1999–2010 Incidence and Mortality Web-based Report. Atlanta (GA): Department of Health and Human Services, Centers for Disease Control and Prevention, and National Cancer Institute; 2013.

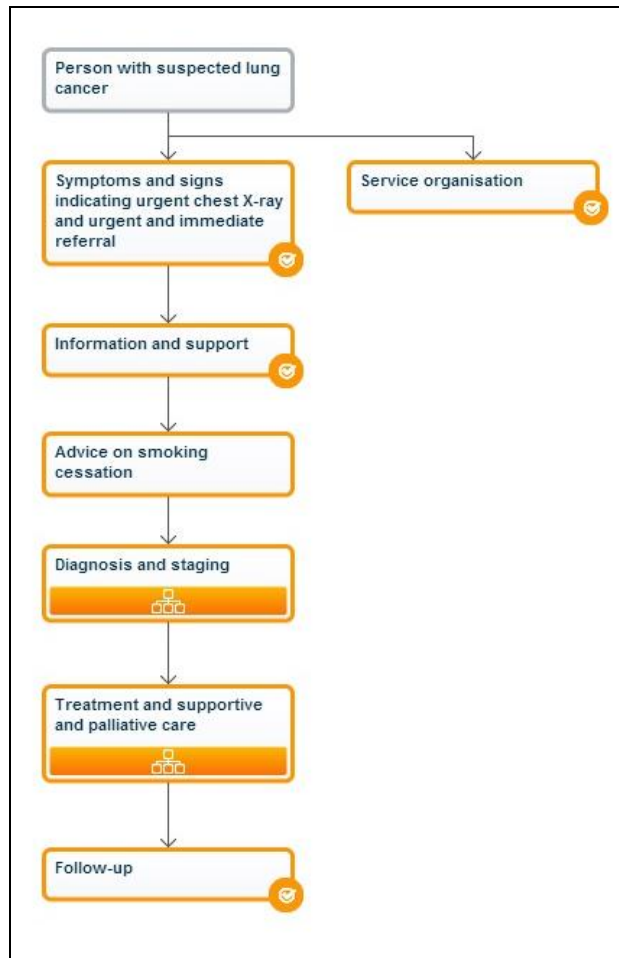


Figure 18 Nice Pathway for Lung Cancer Diagnosis

4.4.4 Guideline Representation Model

The workflow is designed for selected stages of the Lung Cancer guideline using Business Process Modelling and Notation.

1. The process starts by checking if the patient presented Haemoptysis as a symptom. If that is true, the process continues to the next step. If that is not true, the process terminates.
2. The next steps involve checking for the symptoms as described in the guideline. If any of these symptoms are present, the following two activities are required to be done on an urgent basis:
 - a. Offer urgent chest X-ray to patients.

- b. Immediate Referral to Lung Cancer Specialist(Chest Physician)
- c. A diagnosis of Lung cancer is considered.

The Guideline representation model using BPMN is presented in Figure 19.

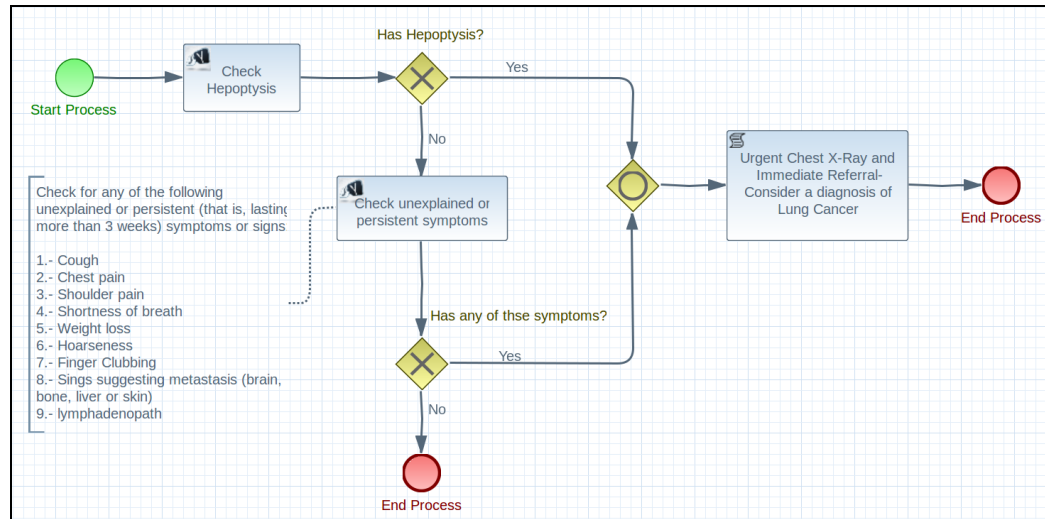


Figure 19 BPMN Representation of Lung Cancer guideline

4.4.5 Guideline Execution Model

The following components of the CDS Framework described in Chapter 3 have been utilized to implement this case study:

- 1. Service Component Architecture:** In this implementation, components representing a particular functionality (in this case medical rules) are defined. A component can either be independently exposed through an external protocol or can be wired together by a process, (a clinical guideline), in a way that is communication protocol neutral (Web Services, Java Messaging Service, Enterprise Java Beans etc). The unit of deployment of SCA is called an SCA Composite. An SCA composite can consist of components, services, references, and wires that connect them together.
- 2. Tolven eCHR™:** To capture patient information and display CDS alerts, the EHR application Tolven eCHR™ is used . This EHR was selected given its user friendly

interface to record and display patient information. Secondly it is an open source platform that allows interoperability with other applications.

3. **Tolven Plugin:** In order to receive and send patient medical data, a Java EE based plugin was developed. This plugin interfaces with Tolven eCHR™, allowing it to receive patient data, transform and validate it against vMR format and transfer the vMR as a web service to be utilized for rules processing in the CDS Rules Service. After the rules have been processed the plugin transfers the desired results (in this case, alerts) back to the EHR
4. **CDS Rules Service:** The CDS rules survive is composed of open source tools and technologies as shown in Figure 20. It includes JBoss jBPM²¹ workflow engine, JBoss Drools²² rules engine, Apache Camel^[23] for message routing and Enterprise Service Bus SwitchYard. SwitchYard provides the SCA runtime.

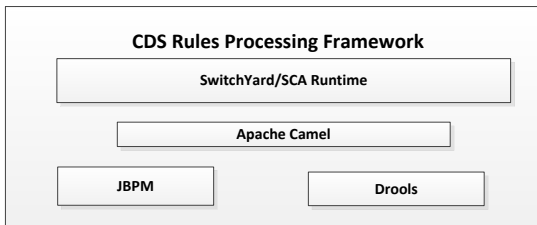


Figure 20 CDS Rules Processing Framework

5. **Eclipse BPMN 2 Modeler:** The clinical guidelines were modelled as workflows using BPMN 2.0, to graphically represent the processes and rules in a medical workflow. The clinical workflow modelled using BPMN is shown in Figure 19.

²¹ <http://jbpm.jboss.org/>

²² <http://drools.jboss.org/>

²³ <http://camel.apache.org/>

- 6. HL7/OMG CDSs:** As a standard for CDS data communication, the HL7/OMG standard for clinical decision support is used. The HL7/OMG Clinical Decision Support Service was designed to enable CDS services to be leveraged using a standard interface. It exposes the CDS functionality as a web service.
- 7. HL7 Virtual Medical Record (vMR):** The HL7 Virtual Medical Record (vMR) is specifically designed to enable mapping clinical data from EHR technologies for use in CDS. It is based on Health Level Seven Inc. HL7 version 3. The version 3 classes encapsulate patient data in a standardized manner. This data includes Patient demographics, problems, test orders, observations, medications and results.

4.4.6 Implementation Methodology

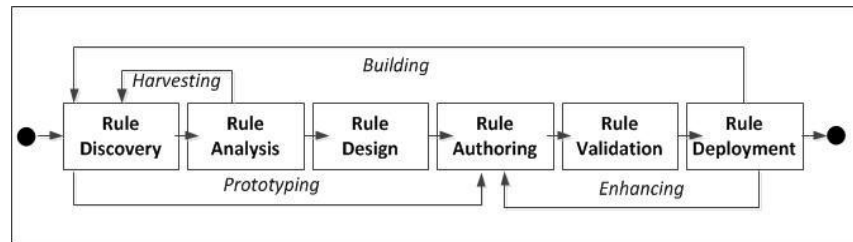
For this project, Agile Business Rule Development Methodology (ABRD) has been selected [98]. This methodology is based on the core values of Agile Software Development. It is an incremental and iterative development approach that considers Business Rules Management and Business Process Management components into business applications. In healthcare, particularly clinical decision support, the knowledge contained in the clinical guidelines may evolve over time, and there may be new information added to the conditions for diagnosis for certain conditions. There is also a requirement for reviewing the content of the CDS (clinical rules) knowledge base by the domain experts such as clinicians themselves, as they will be the end users of the CDS functionality. This necessitates adopting such a methodology like ABRD that facilitates such requirements. Healthcare service delivery is a fast-paced and dynamically evolving industry. Agile Software development is one of the key solutions to developing healthcare applications. The core values of Agile software development methodology and how ABRD addresses these values are shown in Table 8.

Table 8 Agile Development values and ABRD mapping of these values

Agile Software Development Values	Corresponding ABRD Approach
Individuals and interactions over processes and tools.	Rule discovery and analysis requires communication between Domain experts and developers
Working software over comprehensive documentation.	Business users receive an executable set of rules after each iteration
Customer collaboration over contract negotiation.	Domain experts or subject matter experts who are also the end users, are actively involved in the development process
Responding to change over following a plan	Change to business rules is supported by following the iterative approach.

The ABRD approach groups tasks into cycles. These cycles allow the iterative process for development and management of business rules. This methodology consists of six iterative steps starting from Rule Discovery to Rule Deployment as shown in Figure 21.

- 1. Harvesting:** The cycle includes the activities Rule Discovery and Rule Analysis
- 2. Prototyping:** This includes the cycle Harvesting and activities Rule Design and Rule Authoring
- 3. Building:** This includes the cycles Harvesting, prototyping and activity, Rule Validation
- 4. Enhancing:** Enhancing includes the cycles Harvesting, Prototyping and Building and the activity, Rule Deployment.

**Figure 21 Agile Business Rules Development Methodology [6]**

The iterative nature of this cycle ensures that CDS knowledge encapsulated in the rules can be updated as needed. Based on ABRD, the following steps are applied:

1. Harvesting: Identify the rules as reusable CDS knowledge components for the Lung Cancer Diagnosis clinical guideline. In this implementation scenario, the CDS capability is realized by initially, checking for signs and symptoms indicating urgent and immediate referral for chest x-ray in order to reach the goal of early diagnosis. If these symptoms are present for the patient, the necessary recommendations are presented to the physician at the point of care.

- a) Check if the patient presents Haemoptysis as a symptom
- b) Check for the following symptoms (in addition to haemoptysis) as presented by the patient during a physician encounter:
 - cough
 - chest/shoulder pain
 - weight loss
 - chest signs
 - hoarseness
 - finger clubbing
 - signs suggesting metastases (for example, in brain, bone, liver or skin)
 - cervical/supraclavicular lymphadenopathy.
- c) Offer urgent chest X-ray to patients presenting with haemoptysis, or any of the above if unexplained or present and immediate referral to a specialist.

2. Prototyping: Design a model to represents the rules as part of a clinical process and validate the rules against the business logic they represent. The modelling is carried out using Business Process Modelling and Notation 2.0. The clinical scenario identified in the phase 1 of the ABRD is expressed as a process and checking of symptoms as tasks..

3. Building (CDS Processing): Build executable rules, deploy the rules in a runtime environment, and expose them as web services to be consumed by the requesting application. The following CDS Processing steps take place during this phase:

- a) The process initiates as soon as new problems for a patient are entered in the EHR by the physician, and the patient record is modified.

- b) The Tolven plugin collects this patient data and transforms it into HL7 vMR format.
- c) The vMR is then sent as a CDS request to CDS Service . There is a verification performed against the vMR standard conformance for the incoming request.
- d) The problems list encapsulated in the vMR are converted into independent SCA Components. The SCA Composite for Lung cancer guideline is shown in Figure 22. There are two rules associated with this process. 1) Check Hemoptysis and 2) Check Unexplained or Persistent Symptoms (this includes nine symptoms). These components are wired together into a process called “NICE_Lung_Cancer_Clinical_Guideline”. The CDS Rules Service checks if either of these are represented as problems in the vMR. If either of the two conditions is true, a message “Urgent Chest X-Ray and Immediate Referral” is generated and sent as a response to the Tolven eCHR™ interface. This message is shown as an alert to the Physician at the point of care. This message is displayed as an alert to the Physician at the point of care as shown in Figure 23.

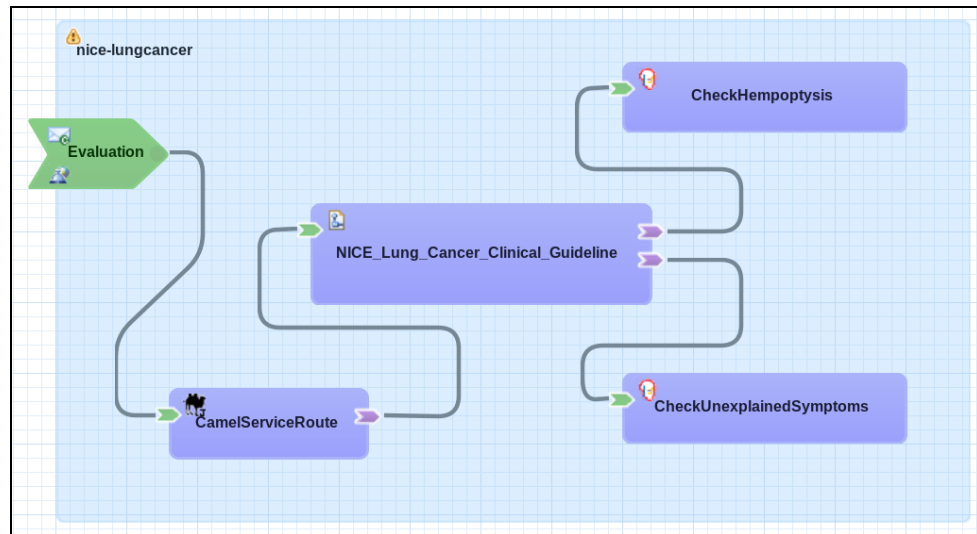


Figure 22 SCA Composite for Lung Cancer Guideline

Problems	Document	Alerts
03/26/2014 Widespread metastatic malignant neoplastic disease (disorder)	ACTIVE	03/26/2014 CDS Service: Urgent Chest X-Ray and Immediate Referral
03/26/2014 Shoulder pain (finding)	ACTIVE	03/26/2014 CDS Service: Consider Diagnosis for Lung Cancer
03/26/2014 Hemoptysis (disorder)	ACTIVE	
03/26/2014 Lymphadenopathy (disorder)	ACTIVE	
03/26/2014 Finger clubbing (disorder)	ACTIVE	
03/26/2014 Hoarse (finding)	ACTIVE	

Figure 23 CDS Capability shown as an alert in EHR

- 4. Enhancing:** Follow an iterative approach to modify existing rules and integrate changes as they appear in a clinical evidence base. This process permits updating the guideline as new or updated knowledge becomes available.

4.4.7 Performance Evaluation

According to the Clinical Decision Support Consortium, an effective CDS service response has to be less than a second [99]. The open source load testing software, LoadUI²⁴ has been used to measure the results of performance testing. The service response times was measured to test the scalability of the service. The service was tested three times for 30, 50 and 60 simultaneous users respectively for a period of five minutes. The results are shown in Table 9.

Table 9 Performance Testing result for Lung Cancer Service

Time (min)	No of Users	No of Requests	Response Time (ms)
05.00	30	881	274
05.00	50	1504	567
05.00	60	1779	987

The average response time of this CDS service is less than a second with a maximum of 60 users. If the number of simultaneous requests are increased, the response time is likely to increase. For managing a relatively small number of requests, this service is suited for integration with an EHR for a small to medium sized healthcare setting. Detailed test results are provided in Appendix 1.

²⁴ <http://www.loadui.org/>

4.5 Results and Discussion

4.5.1 Guideline Modelling Approach

BPMN, which is widely used in industrial enterprise systems modelling, can be successfully used to represent medical processes i.e. clinical guidelines. The possibility of chronological and corresponding graphical representation of clinical guideline process steps provides a structured approach for this purpose.

4.5.2 Knowledge Reusability

The BPMN Processes encapsulate the medical knowledge contained in the clinical guidelines. Since a particular set of symptoms can result in a number of alternate diagnoses, these SCA components representing each process task (symptoms in this case) can be extended to other conditions.

4.5.3 CDS availability at the point of care

The CDS Framework has demonstrated the use of Clinical decision support at the point of care, assisting physicians in making an early diagnosis. The CDS Framework enables the functionality of various components that can work co-jointly to deliver the CDS results to the EHR interface.

4.5.4 Separation of Implementation details from modelling

Using the SCA approach for development and deployment of the CDS framework, the complexities of implementation are separated from the modelling stage of the development. The philosophy upon which the SCA is built is, that clinical functions are available as a series of services, which when wired together create a solution that serve a clinical need like diagnosis.

4.5.5 An Agile framework for implementation methodology

Following methodologies like BPM Process lifecycle and the Agile Business Rules Development (ABRD) approach, an iterative style is adopted which ensures testing and enhancing the functionality throughout the process life cycle thus allowing an enriched knowledge base for medical processes that necessitate an up-to-date evidence base.

Secondly BPM and SOA together provide business agility, thus healthcare organizations can use this approach to respond to the ever changing evidence in the medical and organizational practices.

4.5.6 Managing Complex scenarios

The medical knowledge base built as a result of this process can be maintained in a repository. These components are system agnostic meaning they are not tightly coupled to a particular EHR or development environment. This knowledge can therefore be used in other complex processes.

4.6 Performance Evaluation

4.6.1 Load Testing

The CDS Framework testing on two case studies has delivered sub-second response times. This service was tested with a limited number of users. Hence this framework can currently be installed in a small healthcare facility like General Practice clinic. Performance can be easily enhanced by specifying more powerful computation platforms.

4.7 Conclusion

The CDS Framework described in Chapter 3 is now used to test its feasibility in clinical scenarios. The aim of this research was to provide a mechanism for leveraging a rule-based approach for implementing clinical guidelines to provide robust and flexible clinical decision support. Using a simple modelling approach the physicians and the domain experts can model the rules and processes in a guideline without looking at the implementation details. The clinical knowledge expressed in rules using Drools are human-readable and can be modified dynamically. The BPMN and Rules, can together serve as a CDS Service at the point of care. The Service Component Architecture (SCA) infrastructure provides reusable CDS rules and processes in the form of an SCA Composite. This chapter demonstrates that this CDS service can be integrated with a commercial EHR to provide clinical decision support integrated within a healthcare workflow using the CDS Framework. The proposed architecture successfully automates the processing of symptoms presented by the patient in

the EHR application, hence initiating an alert in the Tolven eCHR™ user interface, calling for an urgent recommendations for early diagnosis. Additionally, the important functionality of reusability is demonstrated by retaining SCA Composite, BPMN and DRL Files, as reusable services. Finally as rules in Clinical Guidelines are liable to changes over time, the use of the BPM Process lifecycle and agile business rules development methodology to monitor and track changes in all the processes that constitute the clinical workflow facilitates rules management and governance over a sustained period of time. In addition to clinical practice guidelines, the functionality of CDS Framework is extended to provide a solution for Public Health Sciences domain subjects such as New Born Screening for genetic disorders. A genetic testing enabled CDS and organizational practice in the next chapter.

Chapter 5

Testing and Evaluation of CDS Framework-
Case Study for Enabling Genetic Data for
CDS at the Point of Care (Genetic Testing
Implementation)

Chapter 5

TESTING AND EVALUATION OF CDS FRAMEWORK-CASE STUDY FOR ENABLING GENETIC DATA FOR CDS AT THE POINT OF CARE (Genetic Testing Implementation)

“It is much more important to know what sort of a patient has a disease than what sort of a disease a patient has.”

- William Osler

5.1 Introduction

With the recent progress in the availability of Whole Genome Sequencing information, the fundamental question arises around the prospects of using this information to improve clinical care. One of the core uses of Genetic information is in the field of personalized medicine. “Personalized medicine is an emerging practice of medicine that uses an individual's genetic profile to guide decisions made in regard to the prevention, diagnosis, and treatment of disease.”²⁵ This is closely related to clinical decision support paradigm that support physicians to make patient-specific decisions based upon CDS knowledge base that guides these decisions. Hence it can be argued that if patient genomic data is added to the CDS knowledge base the resultant CDS functionality will be more enriched and can meet the requirements for personalized medicine. This chapter introduces the idea of enabling a Clinical Decision Support service with Genetic Testing (GT) data. Whole Genome Sequence integration in Clinical Informatics is the future goal for many HIT vendors. Integrating newborn screening results in the clinical workflows is one step of reaching this

²⁵ National Library of Medicine, Genetics Home Reference, Glossary for genetic terms
<http://ghr.nlm.nih.gov/glossary=personalizedmedicine>

future goal. Genetic testing for a large number of genetic conditions is conducted worldwide. The results of this genetic testing can serve to realize the diagnostics and treatment capabilities for many of these genetic disorders. [100] have developed an SOA based solution for enabling CDS guided by genetic data. This scalable architecture has been tested for its feasibility in WGS enabled clinical decision support. This chapter focuses on leveraging that same approach for fulfilling the requirements of newborn screening that are applicable in the current time. This functionally extends the current capabilities of the CDS Framework. A CDS service capable of interpreting DNA Analysis results for genetic predisposition of Cystic Fibrosis in a new born screening sample is designed and evaluated. This implementation also extends the technical scalability of the CDS Framework by presenting a cloud-based approach. The components of the CDS Framework are deployed in the cloud along with the CDS Service for GT.

5.2 Chapter Organization

This chapter consists of the following sections. Section 5.3 reports the availability of genetic testing for CDS, which is followed by the current challenges for genetic testing enabled CDS implementation in Section 5.4. Section 5.5 describes the workflow requirements for this system. Section 5.6 introduces the Newborn screening process for genetic conditions. In section 5.7, the case study for implementing GT enabled CDS is described. Section 5.8 presents the UK's guideline for newborn screening. Key priorities for implementation of this case study are listed in Section 5.9. Cloud based implementation of the NBS Screening case study using the CDS Framework is presented in 5.10. Section 5.11 describes the CDS Framework Implementation of the case study. The solution is tested and evaluation results are presented in 5.12. Results and discussion are described in 5.13 and the chapter is concluded in section 5.14.

5.3 Availability of Genetic Testing for CDS

In modern Clinical decision support systems available either as a separate component or as an integrated part of the EHR, the knowledge base is composed of the data extracted from various sources like Patient demographics, laboratory information system, CPOE systems

etc. The data extracted from these sources and evidence for best practice are processed for providing patient-specific inferences.

5.4 Current Challenges for Genetic Testing-guided CDS

1. **Integrated NBS information management:** The data recorded as a result of the new born screening has to be available for identifying population with genetic conditions. This is possible by allowing an interoperable framework for connecting different data sources like Genetics database, DNA testing results database, Patient demographics etc. for collecting, archiving and disseminating information [101].
2. **Communication process in Clinical decision making in NBS:** The results of the new born screening must be transferred to the relevant resources involved in the care of new born patients. This includes General practitioner, Genetic counsellor, paediatrician and local hospitals [102].
3. **WGS enabled Workflow integration with the EHR:** The HIT in use by the hospitals must include a workflow guided CDS service which facilitates the physician in making timely treatment choices. The different stages in the workflow include, order entry, test tracking, result interpretation, patient notification [103].
4. **Standardised Approaches For managing Genetic conditions:** The implementation of GT enabled CDS must be standards based (e.g. standards by HL7)[104].

5.5 Workflow Requirements for GT enabled CDS:

To enable a Genetic testing results for clinical decision support systems, the following requirements are identified:

1. Need for CDS at the point of care for Genetic disorders like Cystic Fibrosis (CF)
2. Integrate NBS results in the EHR
3. CDS rules for processing results of NBS
4. Providing results of the NBS for screening of CF genes to the physician in the EHR interface in the form of Alerts
5. Alerting the Genetic counsellor in case of abnormal results

5.6 Nationwide Newborn Screening(NBS) Programs

The goal of newborn screening was to introduce a measure for avoiding “Diagnostic Odyssey”²⁶ [105]. Before newborn screening, traditional means of diagnosis for genetic conditions resulted from long journeys from visiting numerous physicians and undergoing a myriad of tests before a diagnosis was made. This was often unhelpful as by the time a diagnosis and treatment plan was prepared, the condition had reached a detrimental stage. The efforts for newborn screening have been initiated on a national scales in many countries. The UK National Screening committee (NSC) is responsible for running the NHS Newborn Blood Spot Screening Programme. The blood spot screening, also called the heel-prick test is performed on all babies in the UK to test for genetic conditions including sickle cell disease (SCD), cystic fibrosis (CF), congenital hypothyroidism (CHT) and several inherited metabolic diseases (IMDs).

In the US, Health Resources and Services Administration has published a report recommending new born screening for 31 specific conditions. The conditions tested in NBS vary by state.

5.7 Case study for Genetic Testing enabled CDS (Cystic Fibrosis)

5.7.1 Overview of Cystic Fibrosis

Cystic fibrosis (CF) is an autosomal recessive disease caused by mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, on chromosome 7²⁷. There are an estimated 1,500 mutations in the CFTR gene.

About 1 in 2,500 babies born in the UK has cystic fibrosis (CF)²⁸, most common amongst North Europeans and their descendants.

5.7.2 Need for NBS for CF:

²⁶ *Diagnostic odysseys* are lengthy, exhaustive, and costly ordeals during which patients with unexplained symptoms travel from one physician to the next, subjecting themselves to an endless battery of tests, often without finding a satisfactory diagnosis

²⁷ Cystic Fibrosis, <http://medical.cdn.patient.co.uk/pdf/1293.pdf>

²⁸ Public Health England, NHS New Born Screening Program <http://newbornbloodspot.screening.nhs.uk/cf>

Most babies born with the condition do not show signs of ill health at the beginning. New Born screening allows for identifying such patients before they start to show symptoms, in order to provide treatment options at a very suitable time. CF is screened by measuring immunoreactive trypsinogen (IRT) in dried blood spots. There are clearly improved outcomes in care and treatment of CF if NBS is implemented on a wide scale as compared to traditional methods based on suspicion and sweat tests resulting in severe malnutrition and chronic respiratory disease [106]. Some of the benefits of early diagnosis and treatment of this condition are listed below:

1. Early instigation of dietary remedies after positive new born screening may lead to long term sustenance to the harmful manifestations of this disease [107].
2. Reduction in days for hospitalization in adult life for children with early diagnosis of CF [107].
3. NBS results and timely treatment therapies influences cognitive development for children with CF [107].
4. As a result of early interventions, Newborn screening for CF may result in improved child survival [108,109].
5. NBS for CF, although leads to initial period of psychological factors such as short-term anxiety in parents, but at the same time, has the potential of lessening inherent long-term negative psychological affects that result from delayed diagnosis like limited options for treatment and lower survival chances [110].

5.8UK's Guideline for NBS for Cystic Fibrosis

The UK Guideline for screening CF is conducted in a number of sequential steps [111]. The two main phases of identifying a population of babies born with Cystic Fibrosis is explained in section 5.8.1 and Section 5.8.2.

5.8.1 Blood Spot Screening Phase

1. **First Blood Spot Sample:** The first blood spot sample is taken when the age of the baby is less than 5 days. Initially the value of IRT in the first blood spot sample is taken. If the

value is above 60ng/ml, the smaller sample is taken for second blood spot and tested for the IRT value. If the IRT value is greater than 70ng/ml, a DNA Analysis is requested.

2. **Second Blood Spot Sample:** The second blood spot sample is taken when the age of the baby is less than 21 days. For second blood spot sample, the IRT value is checked. If it is greater than 120 ng/ml, then CF is suspected for the patient. If IRT is less than 120 ng/ml, the patient is a probable carrier.

5.8.2 DNA Analysis Phase

DNA analysis is conducted for the baby to check for pathogenic CF gene variants. These four gene mutations are:

1. (DeltaF508)
2. (G551D)
3. (G542X)
4. (621+1G>T)

If two of these mutations are detected, then CF is suspected. If one mutation is detected, the DNA analysis is performed to check for panel 29 or 31. If zero mutations are detected, then CF is not suspected.

Other than suspicion and non-suspicion of Cystic fibrosis these results also give an insight to the possibility of probable carrier of CF genes. It is particularly important to maintain these results in the longitudinal record of the patient, as CF gene carrier parents have a one in four chance of giving birth to a child with CF. This is shown in Figure 24:

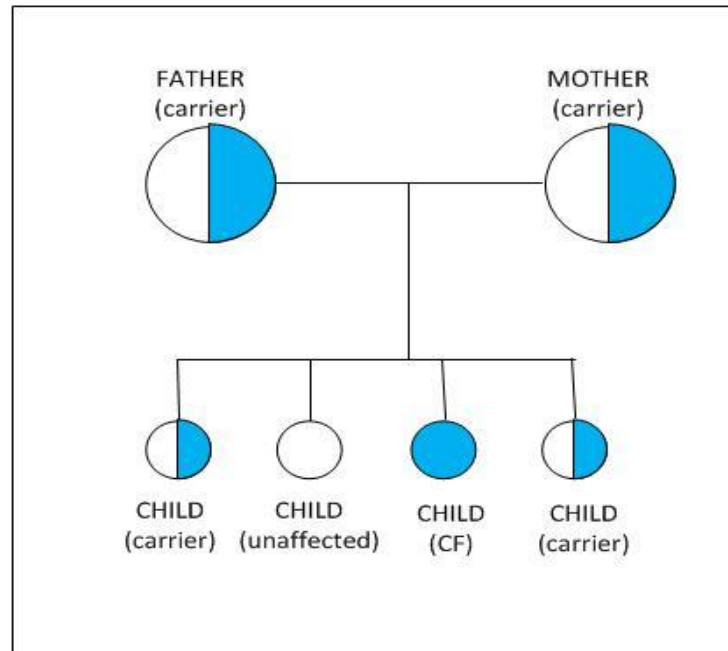


Figure 24 Genetic Inheritance of Cystic Fibrosis

5.9 Key Priorities for Implementation

The testing of the preliminary phase of the guideline Section 5.7.3 is readily available in most of the EHRs. However what is lacking is the availability of DNA analysis phase which can be added as a separate component. The key priorities for implementing such a system are listed below:

1. Testing of DNA sample against the pathogenic gene variants.
2. Availability of recording DNA Analysis results, for a patient ID.
3. A rule-based CDS service capable of providing results like: “CF Suspected”, “CF Not Suspected” and “Probable Carrier”.
4. Transmitting the results of the rule-based CDS service to the EHR
5. Availability of CF Diagnosis or non-diagnosis to the physician’s interface at the EHR at the point of care.
6. Transferring the analysis results to a genetic counsellor
7. An infrastructure capable of connecting systems like CDS service and EHR.

5.10 Cloud Based Implementation for GT Enabled CDS

Across a range of healthcare providers, availability of clinical knowledge base for CDS remains a challenge in the current times. Dixon et.al [112] present a novel approach for implementation of cloud-based clinical data exchange for supporting CDS across disparate healthcare settings. Cloud computing allows a flexible and scalable infrastructure providing storage and processing capabilities dynamically. Applying Clinical informatics applications in the cloud can provide well-timed availability of resources thus reducing operation costs [113]. The implementation of NBS for CF is used as a test case for deploying web based CDS services on the cloud.

5.11 CDS Framework Implementation

Since the CDS Framework is based on Service Oriented Architecture, it allows the flexibility to introduce new components capable to perform additional healthcare-related tasks. The CDS Framework can be extended to add Whole Genome Sequence information for a patient. This includes a data with patient genetic information recorded as a result of DNA testing.

5.11.1 Implementation Methodology

The methodology followed for this implementation consists of the following five steps:

1. Model the process to represent Clinical guideline—*Model DNA Analysis phase for CF Diagnosis using BPMN 2.0*
2. Execute the process- *Using SCA Composite application*
3. Integration between Tolven and CDS Service- *Using SwitchYard ESB*
4. Display the results- *Using Tolven eCHR™ Interface*
5. Notify the genetic counsellor- *Notification Service*

The five implementation methodology steps explained in the Section 5.11.1 are followed in the following phases of the CDS Framework implementation for the DNA analysis phase of NBS for CF.

5.11.2 CDS Framework Components

The following components from the CDS Framework are utilized for this study:

- 1. Tolven eCHR™:** Tolven eCHR™ is responsible to request for DNA Analysis results and displaying them to the Physician at the point of care
- 2. SwitchYard ESB:** The Enterprise Service Bus performs the following functions:
 - i. Send a SOAP message request to the CDS Service based on HL7 vMR standard
 - ii. Receive a SOAP message from the CDS Service with the DNA Analysis results.
 - iii. Check the structure of the response message from CDS service if it complies with HL7 vMR standard.
 - iv. Route this result to the Tolven eCHR™ interface.
 - v. Implement functionality for an Email service
- 3. CDS Service (easyCDS):** For this implementation the CSD service is given the name “easyCDS”. The CDS Service has the following functions
 - a. The business rules for DNA analysis phase
 - b. Performs the evaluation logic for CF Diagnosis
 - i. If zero gene mutation is found, CF is not suspected
 - ii. If two gene mutations are found, then CF is suspected in the patients
 - iii. If One gene mutation is found, then patient is probable carrier
- 4. Tolven Plugin:** The Tolven plugin is used to interface with the Tolven eCHR™.
- 5. KIE Workbench:** The CDS knowledge base (business rules) is created using JBoss KIE Workbench. KIE Workbench combines the functionalities of JBoss Drools Rules Engine and jBPM designer application. It allows project authoring, process modelling, rules authoring, process run-time execution environment and human task interaction functionality.

5.11.3 Deployment of CDS Framework in the Cloud

To test the framework in a cloud environment as opposed to the on-premise environment, two core functionality components of the CDS Framework are deployed in the Google Compute Engine provided by Google Cloud Platform. “Google Cloud Platform enables

developers to build, test and deploy applications on Google’s highly-scalable and reliable infrastructure”²⁹. The two components deployed in the cloud are:

1. EasyCDS Service
2. KIE Workbench (Knowledge base)

5.11.4 Guideline Representation

Business Process Modelling and Notation 2.0 is used to model this guideline. The BPMN model in Figure 25 shows the DNA Analysis phase of the guideline. The process starts with the task of checking for the four gene mutations. The next steps represent the tasks that are executed depending upon the number of gene mutations detected in the DNA Analysis.

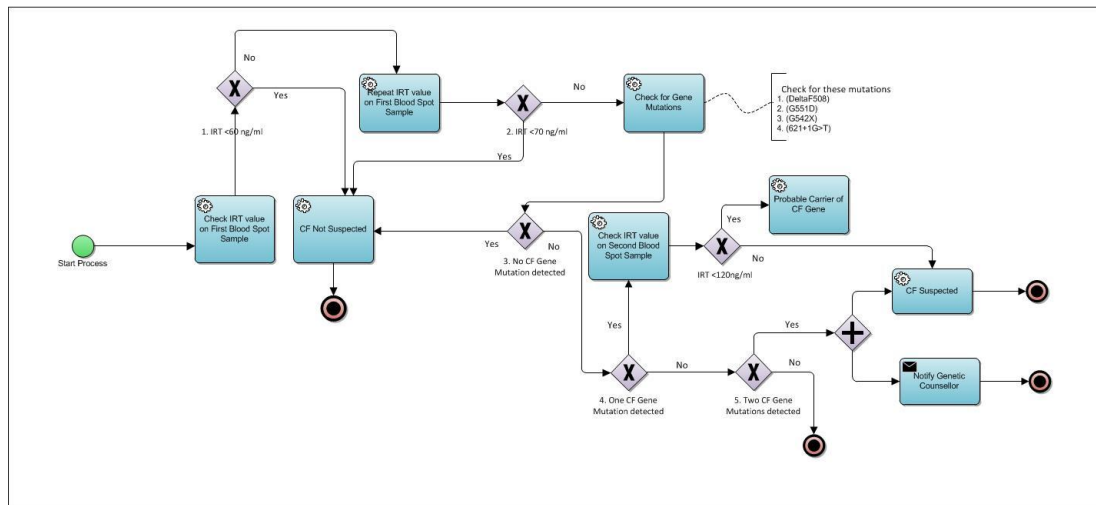


Figure 25 BPMN Model for CF DNA Analysis

5.11.5 Building the Knowledge base (Rule Authoring)

KIE-Workbench is used to define the rules for CDS Service. Using the Rules as described in Section 5.8.2, the knowledge base is defined that encapsulated the business logic for providing CDS results for the result of probability of CF Diagnosis. A screenshot is shown in Figure 26.

²⁹Google Cloud Platform <https://cloud.google.com/>

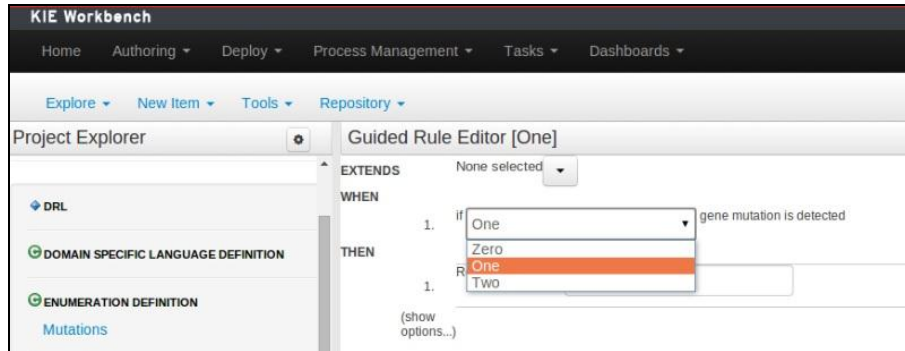


Figure 26 KIE-Workbench Rule Authoring Environment

5.11.6 Guideline Execution

The SCA Runtime environment is presented in Figure 28. The *EvaluationService* realizes the CF DNA rules and results. The *EvaluationService* is the service end point for Tolven.

The guideline execution process has the following steps:

1. Data is received at *EvaluationService*. *CamelServiceRoute1*, sends this data to the *EvaluationEasyCDS* service in the form of vMR payload consisting of DNA data recorded in the Tolven interface. Request also specifies which knowledge base to use against the data being sent from the Tolven interface. The knowledge base is identified by “businessID=easycds-kb” in the Maven repository for KIE-Workbench as shown in Figure 27.

```
<driId itemId="testPayload">
  <containingEntityId scopingEntityId="org.opencds" businessId="easycds-kb" version="0.2.3"/>
</driId>
```

Figure 27 Knowledge base specification in the Repository

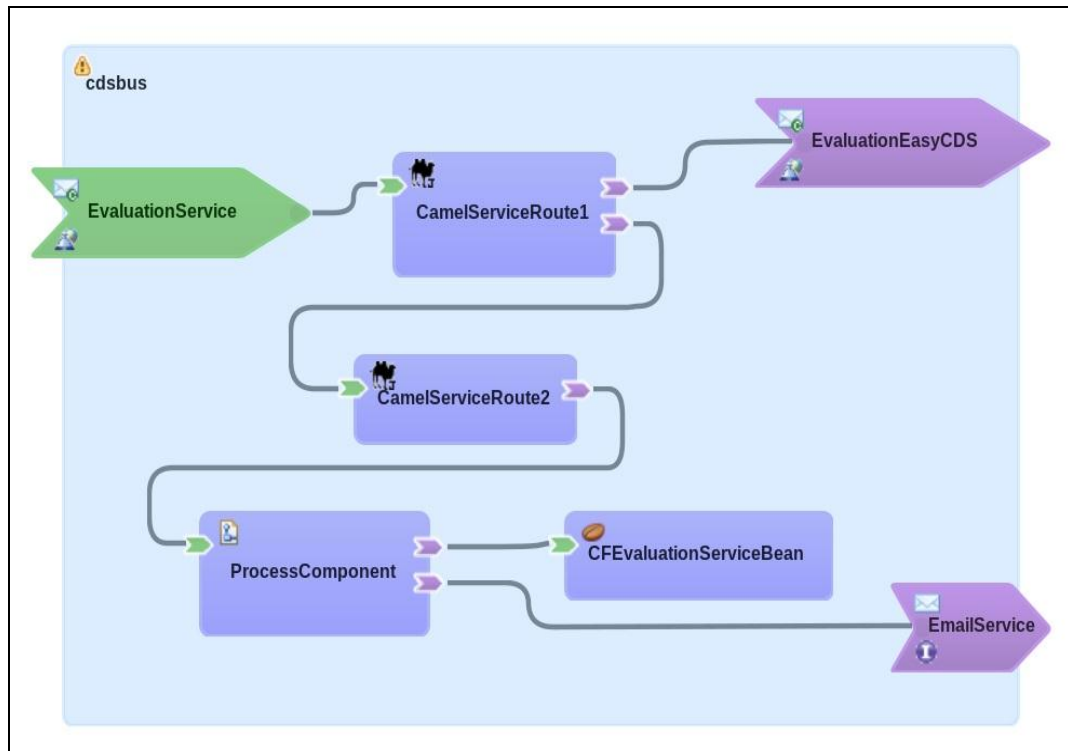


Figure 28 SCA Runtime in ESB for CF DNS Evaluation Service

2. The *EvaluationEasyCDS* services is requested to process the DNA Analysis phase. easyCDS uses the CF Knowledge base that is created by defining rules in KIE-Workbench. The Knowledge base resides in the Maven repository (Location: ***org.opencds .easycds-kb.0.2.3***. (The DRL files reside inside the **-jar** file which is the repository maintained by Maven.) This involves checking the DNA Analysis values entered into the Tolven eCHR™ i.e. the number of gene mutations found (Zero, One or Two)
3. The *EvaluationEasyCDS* provides the processing results to SY component *CamelServiceRouter1*.
4. The *CamelServiceRouter1* extracts the vMR payload from the response and forwards it to the *CamelServiceRouter2* which converts the vMR payload into a Java object.
5. The java object is received by the *ProcessComponent*. The *ProcessComponent* has two tasks, *CFEvaluationServiceBean* and *EmailService*. *CFEvaluationServiceBean* is represented by the task “Check CF Evaluation Task” and the *EmailService* is

represented by “*Send Email*”. The logic encoded in the *ProcessComponent* is represented by the following BPMN process (Figure 29).

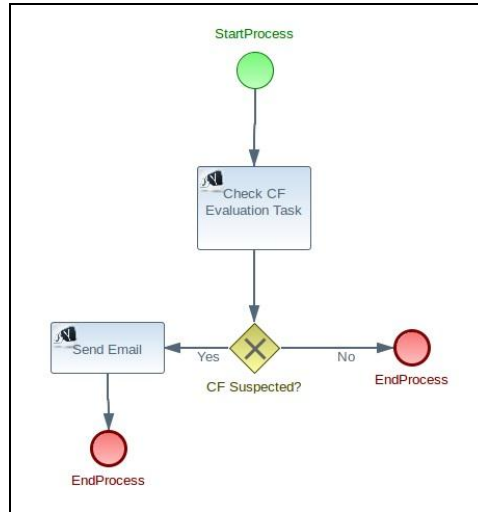


Figure 29 BPMN Process for CDS Evaluation Service

6. The process depicted above starts with the “*CF Evaluation Task*”, that checks if the result obtained from the *EvaluationEasyCDS* is “*CF Suspected*”. According to the logic in decision gateway “*CF Suspected?*”, if that is true then the task “*Send Email*” is executed. This process ends with an email sent to the Genetic Counsellor.

5.11.7 CDS Results

According to the knowledge embedded in the business rules, the CDS results, CF Suspected, Probable Carrier and CF Not Suspected, are displayed in the Alerts section of Tolven eCHR Interface respectively. These results are shown in Figure 30, 31 and 32

Assessments Request Document	Medication List Review New
Discharge Instructions New	Appointments New
Immunizations New	Alerts
Problems Document	08/14/2014 CF Not Suspected
Progress Notes Document	Reminders
Lab Results New	Encounters New
08/14/2014 _CFTR Mut Anal Bld/T 0 Gene Mutation	

Figure 30 Results of CDS Process “CF Not suspected” shown in the Alerts section of Tolven eCHR

Assessments Request Document	Medication List Review New
Discharge Instructions New	Appointments New
Immunizations New	Alerts
Problems Document	08/14/2014 Probable Carrier
Progress Notes Document	Reminders
Lab Results New	Encounters New
08/14/2014 IRT 60 ng/ml	

Figure 31 Results of CDS Process “Probable Carrier” shown in the Alerts section of Tolven eCHR

Assessments Request Document	Medication List Review New
Discharge Instructions New	Appointments New
Immunizations New	Alerts
Problems Document	08/14/2014 CF Suspected
Progress Notes Document	Reminders
Lab Results New	Encounters New
08/14/2014 _CFTR Mut Anal Bld/T 2 Gene Mutation	

Figure 32 Results of CDS Process “CF Not suspected” shown in the Alerts section of Tolven eCHR

5.11.8 Evaluation

The cloud based CDS Service is tested using the LoadUI software According to the Clinical Decision Support Consortium, an effective CDS service response has to be less than a

second. The open source load testing software, LoadUI was used to measure the results of performance testing. The service response times were measured to test the scalability of the service. The service was tested three times for 20, 30, 50, 80 and 100 simultaneous users respectively for a period of five minutes. The results are shown in Table 10.

Table 10 Evaluation testing results for CDS Rules Service

Time (min)	No of Users	No of Requests	Response Time (ms)
05.00	20	200	407
05.00	30	299	424
05.00	50	500	425
05.00	80	802	529
05.00	100	999	874

The average response time of this CDS service is 0.87 seconds with a maximum of 100 users. If the number of simultaneous requests are increased, the response time is likely to increase. For managing a relatively small number of requests, this service is suited for integration with an EHR for a small to medium sized healthcare setting. Detailed test results are provided in Appendix 1.

5.12 Results and Discussion

5.12.1GT Enabled CDS

This Genetic Testing enabled CDS functionality results in a number of advantages when compared to traditional approaches. Firstly, the integration of DNA Analysis phase within the workflow of the physician saves valuable time and resources as an early diagnosis is established and communicated to the relevant actors involved in the treatment of genetic diseases. Thus the clinical decision support functionality is enhanced with genetic knowledge base in addition to standard knowledge bases with standard patient data.

5.12.2 SOA Based Architectural Approach

Using the SOA based approach, the knowledge base is implemented as a separate component from the CDS service. The ESB is only used to route the messages and does not

hold the CDS logic. The CDS Rules are contained in the knowledge base for which the KIE-WB rule authoring and management environment is used. So in order to make changes to the business logic, the rules in the Maven Repository have to be modified rather than the CDS logic in the CDS Service. Another advantage of using the KIE-WB is that a common data model vMR can be imported and used as a basis for the knowledge base. This ensures that the data exchanged for the purpose of CS is standards-based.

5.12.3 Knowledge base Portability

Using KIE-Workbench, one of the key advantages is knowledge base portability. KB-portability is defined as the capability of the KB to be used by multiple applications that are involved in the CDS functionality of a HIT. This concept is realized by the fact that knowledge base is separated by the CDS Functionality. It is maintained using the Maven Repository specifications. The Maven repository is maintained in a specific Group and allocated a Group ID. An independent project (a separate KB in another project) can use this knowledge base by accessing this Group ID. For example, the Maven repository can be cloned and used in a separate KIE-WB project, thus allowing the reusability of the existing knowledge maintained in the KB. Secondly it defines a versioning mechanism for Knowledge repositories, so that when a modification is applied to a KB, it can be maintained as a new version. The version history is a useful tool to trace the changes made in a knowledge base.

5.12.4 Applying the concept of Code Extensibility using GIT to clinical knowledge base

This implementation has utilized GIT for source code management. GitHub³⁰ is an online repository for maintaining versions of source code. The code can be updated as required by a healthcare IT implementation. Clinical knowledge bases can be maintained and updated following the same principle.

³⁰ <https://github.com/>

5.12.5 Reproductive Risk

This study can be extended to assess reproductive risk for parents who are carrier of the CF gene. CF DNA Analysis is carried out on both the parents. If they both show positive results for CF Carrier, then there is 1 in four chance that their baby will be born with the condition. On a similar note, the information for a child with the DNA analysis result of “CF Carrier” can be stored in the longitudinal record for future references especially multifactorial³¹ diseases.

5.12.6 Cloud based implementation

Cloud based implementation of the CDS Framework provides solution to many of the prevalent healthcare technology implementation challenges. Such as increased collaboration between multiple health service providers to meet the demands of availability and sharing of clinical data. Secondly, by storing patient data in the cloud, critical information can be accessed by healthcare professionals even when they are not in the premises of the healthcare setting. There is automated provisioning of resources, thus allowing scalability of the healthcare applications. Secondly, the performance results have improved significantly after hosting this service on the cloud.

5.12.7 Notification Service

In case of abnormal results such as “CF Suspected”, along with an alert to the physician at the point of care, an email is sent to the Genetic Counsellor to notify them. This is an additional capability provided by the CDS Framework to allow swift communication between the different actors involved in the newborn screening process.

5.13 Conclusion

This chapter has presented a cloud-based implementation of the CDS Framework with the aim of providing CDS Functionality that is guided by Genetic Testing. The achievements of this chapter are two-fold. Firstly, with the goal of Whole Genome Sequencing provided

³¹ Diseases that are caused by a combination of factors are described as multifactorial. These include a combination of genetic factors as well as lifestyle and environmental factors.

as a part of HIT in future, new born screening has been adopted as a test case to validate the feasibility of genetic testing enabled CDS to meet the current needs in the field of Genomics. Secondly, the functionality of the CDS Framework has been enhanced by deploying the components of the architecture solution in a cloud environment, hence reducing the costs for managing resources and automating the orchestration of the different components of this framework. Also, hosting the CDS Service in the cloud enabled the availability of newborn screening CDS Functionality amongst multiple healthcare settings. The rules can be modified to test for various conditions that are a part of newborn screening process. The load testing results fulfil the sub second response time for an efficient CDS Service. These results can be improved by adding more resources to the project. Privacy of data is ensured by existing security features provided by Red hat Enterprise Linux platform. In future security regulations such as those developed by Health Insurance Portability and Accountability Act (HIPAA)³² can be added to the healthcare cloud infrastructure.

³² HIPAA Privacy rule and Public Health <http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm>

Chapter 6

Testing and Evaluation of CDS Framework-
Case Study For Collaborative Healthcare
Management (Organizational Practice)

Chapter 6

TESTING AND EVALUATION OF CDS FRAMEWORK-CASE STUDY FOR COLLABORATIVE HEALTHCARE MANAGEMENT (*Organizational Practice*)

*“Apprehension, uncertainty, waiting, expectation, fear of surprise,
do a patient more harm than any exertion”*
-Florence Nightingale

6.1 Introduction

The previous chapters in Part 3 of this thesis present case studies for testing and evaluating the CDS framework in Clinical Practice by automating clinical guidelines and enabling CDS at the point of care. In addition to support for clinical practice, the CDS Framework is enabled to support organizational processes by introducing the functionality of “*Human Task Management*”. A vital feature of Business Process Management is human task management which is the ability of an information system solution to allow interventions from human actors with the computerized workflows to achieve a business goal. For example in an HR information system, an employee may put up a request for a raise in salary. This is the kind of activity that will require a human intervention for approval in addition to an evaluation activity, which an HR information system is already capable to perform automatically. To achieve this goal, the HR system will first perform an evaluation based on the employee data in the system. After that an intervention will be required by the manager to approve the process. Such a system will allow notifying the manager that there is an input requirement from him for this task to be completed by providing an interface to

the manager to perform this task. In healthcare, a large number of examples of human interventions in an automated process exist. A common example of such a scenario is an Emergency Department (ED). This chapter presents a modelling solution to allow a human task management component using the CDS Framework, thus enhancing the capabilities of the CDS framework for management of administrative processes in an Emergency Department. The medical and organizational processes in the ED are separated and a BPMN model is presented to allow coordination among several resources to provide treatment for patients. The UK NICE Guideline for managing acutely ill adults is implemented as an example scenario.

6.2 Chapter Organization

The chapter is organized in the following sections. The problem is defined and discussed in Section 6.3. Section 6.4 highlights the major observations made regarding drawbacks in current practices in the ED resource management and resultant issues in patient care delivery. Section 6.5, provides an overview of the potential of BPM and SOA together to address the problems in ED resource management and provides an architecture overview of the solution. Section 6.6 introduces the NICE Guideline for acutely ill patients. Section 6.7 presents the key priorities for implementing the guideline. Section 6.8 provides the implementation methodology. 6.9 presents the guideline representation and execution model in light of the CDS Framework. 6.10 presents the results and discussion and conclusion are given in 6.11.

6.3 Motivation

One of the fundamental requirements of an Emergency Department in a hospital is to provide efficient and timely treatment to its patients. Given the diverse nature of problems presented by the patients, it often becomes an overwhelming situation for the responsible resources to provide immediate services to the patients. This requires an agile and collaborative effort from all the actors involved in the care delivery process. These actors include humans (Physicians, nurses, critical response teams) and computerized systems (EHR applications and emergency evaluation systems).

With the recent advancements in HIT, many EDs are equipped with the necessary infrastructure to allow these resources to connect with one another. However these systems lack the functionality for allowing human actors to intervene and update the process that forms the basis of these systems.

6.4 Current Challenges in Emergency Care

6.4.1 Patient Flow

In Emergency healthcare, Patient flow is “the movement of patients, information or equipment between departments, staff groups or organisations as part of a patient's care pathway” [114]. Constraints to Patient flow can cause a number of problems in the patient care at a time of critical importance. Adapted from [115,116] these are listed as follows:

1. **Unscheduled Patient care:** The ED is underprepared to address the needs of unscheduled patient visits. If the hospital does not have a procedure in place, the management of such patients becomes very difficult
2. **Mismatched demand and capacity:** Physical layout of the ED and availability of the appropriate number of medical staff does not support huge patient number demands
3. **Unavailability of Patient Data:** To perform ED tasks, there is a need for timely availability of a patient’s medical record. This is usually not possible because of lack of connectivity between different health information systems. Information such as comorbidity and drug allergies should be readily available to assess the patient and provide the right care.
4. **ED Resource Identification:** To meet the needs of emergency care, the available resources (emergency specialists, critical care nurses) information must be available to the resource attending the patient in order to make an immediate referral and save time.
5. **Resource Allocation:** If the information of the available emergency care resources is available, the attending resource must be able to allocate the patient to the resource involved in the next steps on the treatment pathway. There is a need to facilitate this process by allowing notifications to the right resources, in order for them to act swiftly.

6. Separation of Administrative and Clinical processes in ED: The care processes in an ED are multidisciplinary in nature in the sense that they involve administrative (admission, allocation to specialists, approval of medications etc.) as well as clinical processes (labs, imaging etc.) This relationship is shown in Figure 33.

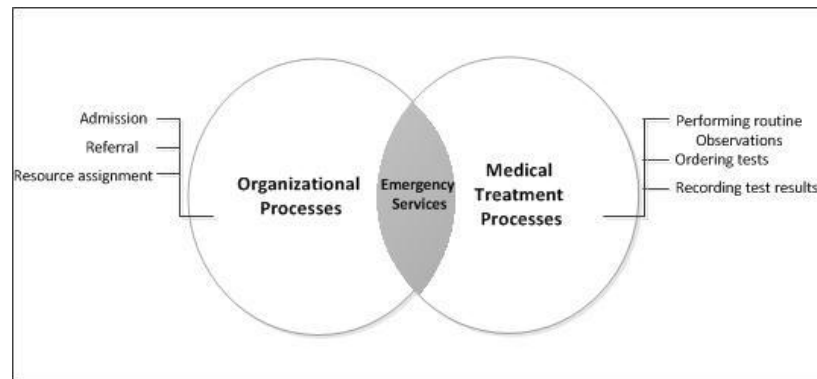


Figure 33 Multidisciplinary relationship between and Organizational and Treatment Processes for ED

7. Application Integration: Application Integration across different information systems in a hospital is a major issue in enabling smooth patient flow [117]. Because of lack of interoperability across these diverse information systems (Laboratory Information System, Patient Administration System, CDS Systems etc) the patient data cannot be connected and become readily available as the resources need them.

6.4.2 Human Interaction Workflows

Human Interaction workflows are defined as “the type of workflows in which humans are actively involved and interact with information systems” [118]. An ED workflow is an example of such a workflow given the nature of continuous interaction from human actors with the computerized actors facilitating the ED care. Emergency Department’s workflows require robust coordination between resources for treatment, referral, admission and discharge processes in order to maintain a swift and accurate patient flow through the different stages during their ED visit. Constraints to patient flow in EDs are mainly due to patient waiting time. A computer-based real-time analysis tool can address the problem of coordination of various ED resources to decrease patient wait times [117].

6.5 Potential of CDS Framework in ED Process Management

As specified in Chapter 3, The CDS Framework is built upon exploiting the industry best practices of SOA and BPM tools and techniques. The following gives a brief account of the capabilities of SOA and BPM combined together:

6.5.1 SOA

A SOA based implementation of modern Healthcare IT infrastructures provides the advantage of a loosely coupled solution. This allows sharing of resources among different modules that make up the HIT for a healthcare organization. Web service based implementation enables long-term reusability and portability of the systems. The different components of a healthcare IT infrastructure are connected through an enterprise integration platform (Enterprise Service Bus).

6.5.2 BPM

One of the available technologies provided by Redhat is JBoss jBPM Console. This feature allows for adding human task management service to an existing clinical process. It allows the user to implement a guideline as a process, decomposing each step of the process as a task, and monitor the whole lifecycle of the task starting from initiation to completion. It is a standard-based implementation using OASIS's WS-Human Task Specification. This specification is explained further in Section 6.5.3.

6.5.3 Human Task Management Service

The WS-Human Task specification was created to allow human intervention in SOA based applications to eliminate the otherwise tightly coupled human tasks in a workflow management system [78]. This specification permits the user to interact with the workflow as a separate component, outside of the automated workflow. It has two main components:

- 1. Task Processor:** Similar to a workflow management system that uses a task processor to manage the sequence of tasks in a business process, this task processor can be utilized independently to manage human tasks in a human task enabled component.

2. **Interface:** There must be an independent interface for the human actor in a workflow to provide his input and that can be later integrated with the automated workflow.

6.5.4 Combining SOA & BPM

Chapter 3 describes implementing Service Composite Architecture as a fundamental technique to implement the SOA based CDS Framework. CDS Framework enables the BPM processes to be executed using a web service implementation. Figure. 34 shows an overview of how BPM and SOA can together work to provide a loosely coupled solution:

1. In the CDS Framework, healthcare enterprise application infrastructure is based on the SOA paradigm. The functionality of healthcare enterprise applications is provided by implementing web services. At the bottom layer of this architecture, are the data sources for different healthcare enterprise applications like LIS, PAS, A&E etc. At the top layer are the SCA Composite applications that invoke the health enterprise web services that realize the functionality of these healthcare enterprise applications. In case of the CDS Framework, the enterprise service bus SwitchYard is used to provide integration at the middleware level. It is also at the ESB level, that the EHR Interface (Tolven) is accessed.

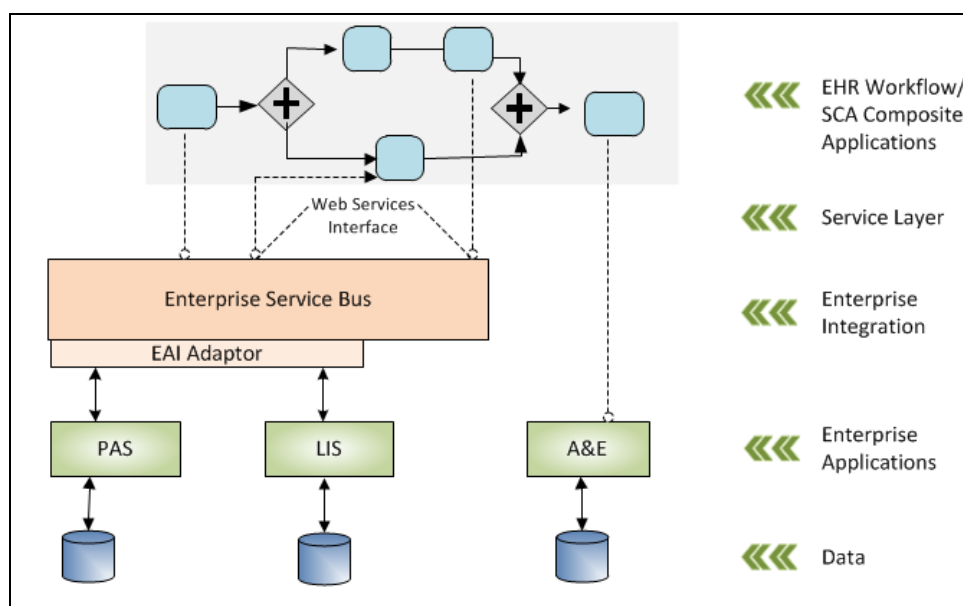


Figure 34 SOA Based infrastructure for Healthcare Workflows

2. Using BPM, a routine clinical workflow is first modelled and then executed using the SCA Composite Application. A Routine ED Workflow modelled using BPM specification is shown in Figure 35.

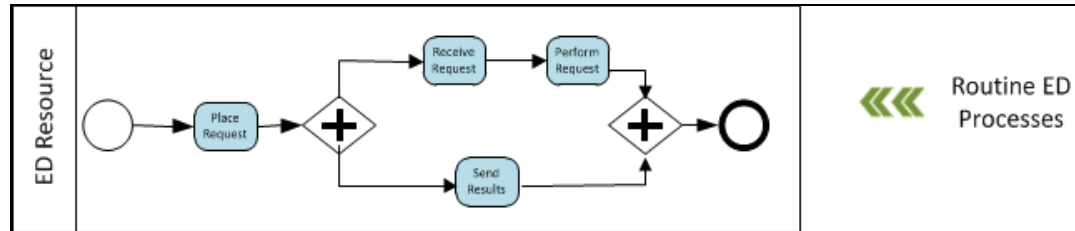


Figure 35 Routine ED Workflow modelled using BPM specification

3. The human interaction workflow can be inserted in the middle of the first two components. The functionality of the human interaction workflow can be realized by human actors (managers, physicians, nurses) as shown in Figure. 36

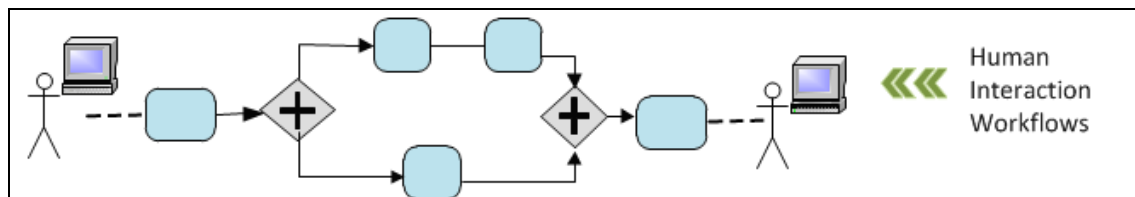


Figure 36 Routine ED Workflow modelled using BPM specification with Human Interaction

4. The above three components depicted in Figure 34, Figure 35 and Figure 36 can be combined to provide a high level view of how the Human Interaction Workflow can fit into the CDS Framework as shown in Figure 37. The jBPM console allows initiation of this human task service using a REST API [119].

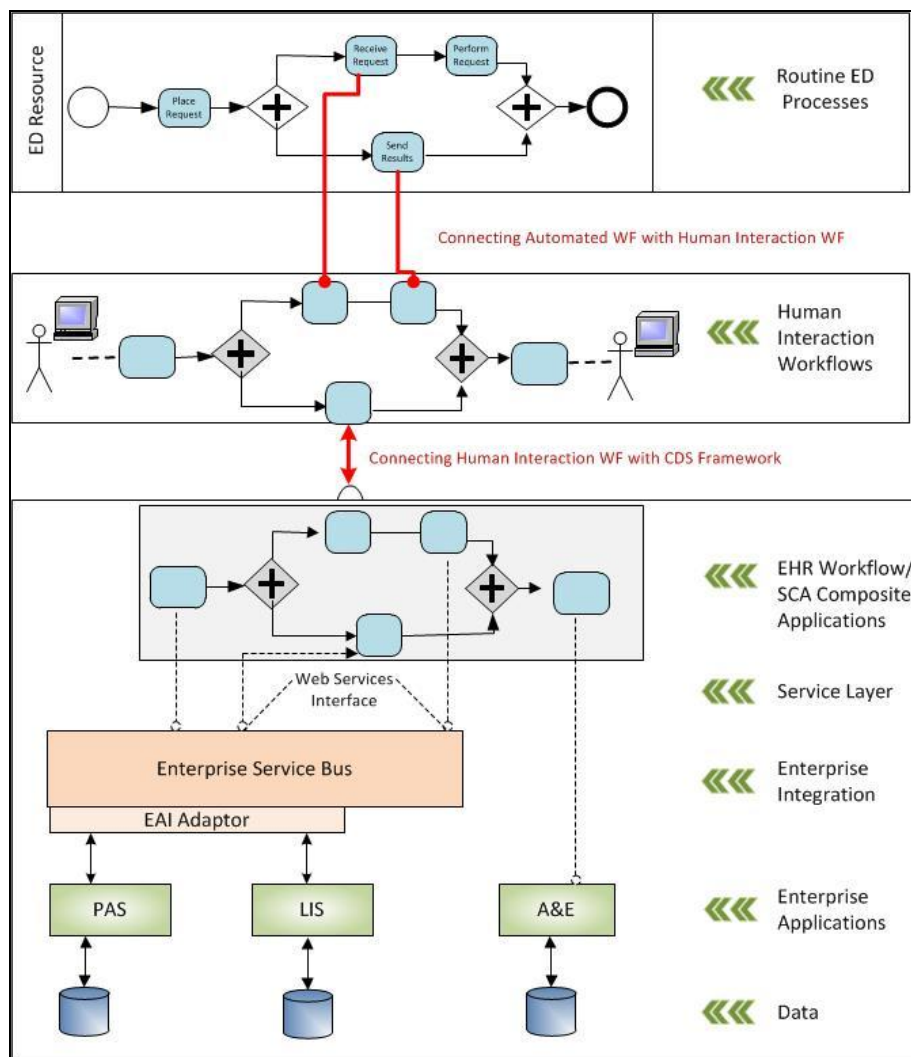


Figure 37 High level Architecture of a Human Interaction workflow enabled CDS Framework

6.6 NICE Guideline for Acutely ill patient in ED

6.6.1 Guideline

The UK NICE's guideline for acutely ill patients presents the treatment and monitoring pathway for patients in an acute setting i.e. Emergency Department [120]. This guideline is specified for the care of adult patients and covers the steps for the complete encounter for emergency care provided to a patient. This is an evidence-based guideline last updated in December 2010, supported by full guidance documentation.

6.6.2 Actors and their responsibilities

For the purpose of implementation, three actors (human and computerised) are identified.

1. **Admitting Doctor (Human):** The admitting doctor performs an initial assessment for the patient and takes the decision for admitting the patient in the ED setting. The doctor takes into account diagnosis, comorbidities and agreed treatment plan. The admitting doctor is also responsible for creating a routine monitoring plan like recording vital signs.
2. **Bedside Nurse (Human):** The bedside nurse is responsible for the routine monitoring for the patients as specified by the admitting doctor. They manage the tests (labs, imaging) for the patient as ordered by the admitting doctor and record the results of the routine monitoring into the Physiological Track and trigger system (PTTS). They receive the score results from PTTS and inform the responsible team according to the scores allocated by the PTTS.
3. **Physiological Track and Trigger System (PTTS):** The Physiological Track and Trigger System (PTTS) is a software information system, which provides an interface for the bedside nurse to record the routine monitoring and test results. The PTTS processes the input and results in a graded score that determines the severity of the patient's condition and hence guides the nurse to contact the appropriate response team.

6.6.3 Graded Response Strategy

This guideline is based on a graded response strategy for the management of the acutely ill adult patients. Based upon the input entered by the bed side nurse in the PTTS, the patients are assigned one of the four score groups by the PTTS. The bed side nurse is then responsible for contacting the relevant resources to manage the patient according to the severity score. The resources responsible for treating the patients according to the score group are presented in Table 11.

Table 11 Graded Response Strategy Score and Resource Assignment

	Group	Responsible Resource
1	Low Score	Nurse in-charge
2	Medium Score	Admitting Doctor, Critical Care Outreach team, Critical Care trainee
3	High Score	Emergency Critical Care Practitioner
4	Critical Emergency	Emergency Critical Care Practitioner, Cardiac Team (if Cardiac arrest)

6.7 Key priorities for implementation:

Using the CDS Framework described in Chapter 3, the above scenario was automated and human task management capability was implemented using Business Process Management techniques and Service Component Architecture infrastructure. The CDS Framework's capabilities were extended by adding the human task management component. In order to take advantage of this architectural solution, the following requirements were identified:

1. The modelling solution allows the creation of users at different levels such as Managers, Physicians, and Nurses etc.
2. After successful sign in, the system prompts the user to view the outstanding tasks
3. The modelling solution allows user to select the task and mark it as *Complete, In Progress, Deferred or Completed*.
4. The managers are allowed to view all the tasks that are initiated or are in progress in the workflow.
5. The manager should be allowed to allocate different users (resources) to a task.
6. The modelling solution should highlight the task in progress so that the physician or manager can monitor the progress.
7. The guideline is automated as a business process
8. The model should allow differentiation between User Tasks and System Tasks
9. The model is available as a web service
10. The workflow model should allow a web service interface to interact with other healthcare information systems
11. The model should allow integration with an existing infrastructure in the ED.

12. The model must be flexible to allow changes to the processes or tasks.

6.8 Implementation Methodology

For the implementation of the ED workflow capable of supporting human task management, “Pattern-Based Cycle for E-Workflow Design” is selected as the methodology [121]. The rationale for selecting the methodology is based upon the following considerations:

1. ED is a multidisciplinary practice organization that includes administrative, support and medical processes.
2. There is a need to separate different types of processes in order to devise a process model that maps the ED practice.

This methodology provides a cycle-based approach to model a workflow based upon separation of four perspectives involved in an electronic workflow. These four views are described as follows:

1. **Functional Perspective:** Functional perspective is related with the process functionality of the organization. The processes are broken down into tasks.
2. **Organizational Perspective:** The organizational perspective specifies the roles to which the organizational functions (processes and tasks) are assigned
3. **Behavioural Perspective:** This specifies how the information is routed through the different steps in the workflow.
4. **Informational Perspective:** The informational perspective describes the organization’s data, knowledge base, structured documents and standards specification, which are formed and utilized within the organization.

Some examples of ED processes according to the above perspectives are listed in Table 12.

Table 12 Tasks categorized according to definitions of the four steps for the e-Workflow design life cycle

Functional	Organizational	Behavioural	Informational
Admit Patient	Assign ED Resource	Contact ED Resources	Patient Record
Perform Assessment	Transfer patient	Assign group	Resource Information
Perform Monitoring	Ward management	Contact departments	PTTS results
Treatment Plan	Update Available Resource	Record Results	Test Results

6.9 CDS Framework Implementation of Guideline

6.9.1 Guideline Representation Model

Business Process Modelling and Notation 2.0 is used to graphically model the guideline, as shown in Figure. 38. The three actors are presented in three swim-lanes. The process starts with admission of the patient into the ED by the doctor (shown as a user task). The bed side nurse is responsible for contacting the relevant resources in the ED based upon the results obtained from the application, physiological track and trigger system (PTTS), which assigns a criticality score group, namely: “*low*”, “*medium*”, “*high*” or “*critical*”, to a patient. The PTTS is shown as a system task. The three actors are modelled to present a collaborative healthcare scenario.

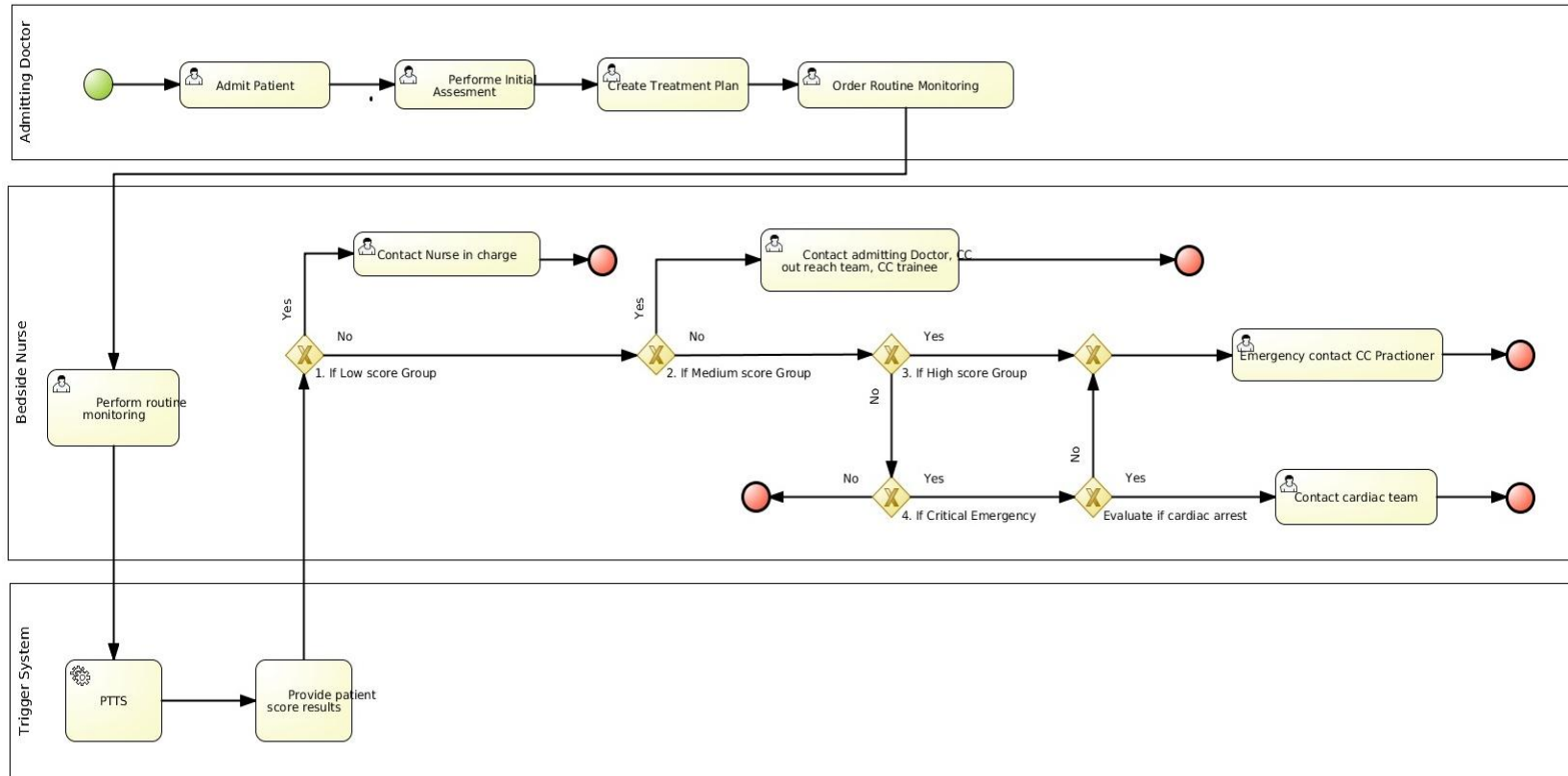


Figure 38 BPMN model of e-Workflow for ED Resources

6.9.2 Guideline Execution Model

This model allows users at different levels in the hospital (administrator, physician, nurses etc.) to track the status of the patient. The security of the patient data is ensured by the system's user rights mechanism, which provides different features (order, accept task, finish task etc.) depending upon the rights available to a range of diverse roles in a hospital. Each user logs into the systems with their own username and password. The system provides a list of tasks available to be performed. The user accepts the task and enters the information when it is completed. The next task is then highlighted and the responsible user is sent a notification to log in and record the progress of the task.

6.9.3 Guideline Execution with the existing CDS Framework

The jBPM implementation of the ED allows interaction with the CDS Framework by introducing a web service interface. This enables the system task (PTTS) to access the data from the EHR by establishing a connection with the ESB. The Tolven Plugin enables extracting patient data from the EHR. In this way, the patient data can be accessed at the human interaction workflow level.

6.10 Results and Discussion

This chapter has provided an example of the addition of a human task management service for managing human interventions in a medical treatment process. This modelling solution provides a mechanism to solve the constraints to patient flow, especially by managing and assigning the right resources at the critical time to address the emergency needs of the patient. By mapping the guideline based ED medical and organizational scenario, this solution provides the hospital administrative and medical personnel with the facility to start new process instances as well as examine the state of currently running ED processes. The tasks assigned to human actors can be retrieved based upon access rights and completed using task lists assigned to them. Additionally, reports can be produced built on the doctor, nurse or critical care team's outcome. The knowledge required and produced by these resources is maintained in the processes, which addresses the problem of insufficient

communication and missing information allowing smooth patient flow during their time in the ED. The advantages of combining SOA best practices and BPM are realized in the following ways:

- 1. Interoperability:** An SOA based solution provides interoperability among the different components used to automate the ED workflow.
- 2. Portability:** The human interaction workflow is implemented as a separate component, which can be used as an independent application from the EHR to allow a timely and swift response to the management of resources in the ED. This allows for users to log in to this application and manage the process whether they are on the premise or away from the acute care setting.
- 3. Simple Graphical Representation:** The simplicity of the BPMN model allows for non-technical users (business users i.e. physicians) to make changes in the process.
- 4. Loose coupling:** This solution is not dependant on the working of the other information systems used in the hospital setting. It is implemented as a separate component. It is possible to update a step without having any impact on the rest of the process.

6.10.1 WS-Human Task Specification:

- 1. Notification:** The WS-Human task specification facilitates the notification to the users of the system. This is critically important for the users in an ED setting.
- 2. Escalation:** If the responsible user does not respond in the specified time, the next available resource is automatically allocated to the patient to take action and prevent delay.
- 3. Collaboration Protocol:** The WS-Human Task Management standard allows for coordinating tasks/activities across multiple divisions in an organization.
- 4. Rendering:** The interface of this solution can be adapted according to the device the user is using at the time. For example, portals for web-based interface, application interface for mobile and tablet users.
- 5. Mapping Life cycle of the tasks:** The complete life cycle of the task in an emergency department is mapped such as creation of a task, claiming the task by the responsible resource and completing the task.

6. Attachments: The users can also add attachments in the form of reports and images. Consultation notes and discharge summaries.

6.11 Conclusion

Using the jBPM Human task Management Service, this chapter demonstrated that by enabling human interaction in ED workflow, the key factor of human interaction for BPM can be addressed. The implementation of the human task management service is based on WS-Human Task specification, provided by OASIS. The application of the CDS Framework is extended to Human Task Management functionality. Additionally, given its ease of use and simple representation using BPMN, changes can be incorporated into the workflow by actors at the business level rather than technical developers. This facilitates adaptation to the evolving nature of healthcare workflows. Secondly, the process defined in one medical scenario such as ED, can be reused for other medical scenarios. Facilitating an ED with evidence-based guideline-centred sequences of actions, this solution provides an enriched outlook of the patient flow ensuring a decrease in the treatment gaps, reducing redundant tasks and integrating human work with the available information systems. This chapter provides a modelling solution and future work involves execution of this model with real-life scenarios from the Emergency Department.

Part IV: Conclusion

Chapter 7 Conclusions and Future Work

Chapter 7

Conclusion and Future Work

Chapter 7

CONCLUSIONS AND FUTURE WORK

The main objectives with SOA initiatives is to enable a more agile, flexible and standardized approach to designing, developing and deploying functionality that is often scattered through established IT systems.

–Gartner Inc, September 2005

7.1 Summary

This thesis proposes a framework which is assembled by leveraging the SOA and BPM techniques. The case studies are a proof of concept for the implementation of the CDS framework. The case studies can be extended to an enterprise wide implementation given the availability of hardware and technological environment requirements for a large-scale implementation.

7.2 CDS Framework Benefits

- 1. Bridge design-time/Run-Time divide:** From the point of view of the developers, having access to documents that describe the functionality of the code in a run-time environment can result in improved architecture design and implementation. Process models are one way of achieving goals.
- 2. The importance of Systems Modelling:** In the healthcare domain, models for clinical and non-clinical processes are created by a number of people including the participants of the actual clinical processes. It is imperative that these models are made consistent with the goals of the software architect as well as those of the healthcare organization. Models provide a standard against which the performance of the automated business processes are measured. Modelling is a progressive activity that evolves and becomes less abstract as the systems are matured.

3. **Strategic Benefits:** Applying SOA to the healthcare organization when implementing a technology strategy, the benefits are many-fold. Using services to implement the functionality of healthcare enterprise, the complexity of the processes can be reduced, as services can be used multiple times. Standards-based services increase the organizational agility, as it allows accommodation of changes in the business processes of the organization.
4. **BPM and SOA Grouping for Enterprise wide implementation in Healthcare:** The literature survey identified the potential of combining SOA and BPM best practices for achieving a healthcare organization's strategic goals. An SOA based implementation for CDS guided by BPM techniques like modelling clinical guidelines results in delivering organizational agility.
5. **Business Value of Open source Infrastructure:** Adopting Open Source Implementation infrastructure for the technological implementations of an organization ensure innovation and flexibility. It directly leads to lowering up-front investment costs. Shared development team across different departments of an organization promotes high levels of creativity and agility.
6. **Auditable HIT Implementation:** Using BPM and rule-based architecture, the processes and rules for a HCO can be used for showcasing its IT infrastructure. Modelling processes using BPMN like Clinical guidelines and administrative guidelines can serve as an artifact at the time of audits by a regulatory body for healthcare IT. BPMN models are used extensively for compliance testing in industries like banking and manufacturing. For medical processes, auditors assess the compliance against regulations by taking samples of data that is either used as an input or the resulting data from medical processes. This SOA based IT infrastructure can be assessed in the following ways:
 - a. Since the SOA based architecture solution is composed of loosely coupled independent components, the functionality of each of these components can be tested without stagnating the performance of the other components.
 - b. Testing each component independently can be vital to identify and track implementation bugs/errors, thus allowing timely technical issue management.

- c. Owing to the simplicity of BPMN representation of business processes, the domain experts can modify the process models as soon as they identify a flaw without affecting the implementation functionality.

7. Clinical knowledge base Portability: Using KIE-Workbench, one of the key advantages is knowledge base portability. KB-portability is defined as the capability of the KB to be used by multiple applications that are involved in the CDS functionality of a HIT. This concept is realized by the fact that the knowledge base is separated by the CDS Functionality. It is maintained using the Maven Repository specifications. The Maven repository is maintained in a specific Group and allocated a Group ID. An independent project (a separate KB in another project) can use this knowledge base by accessing this Group ID. For example, the Maven repository can be cloned and used in a separate KIE-WB project, thus allowing the reusability of the existing knowledge maintained in the KB. Secondly it defines a versioning mechanism for knowledge repositories, so that when a modification is applied to a KB, it can be maintained as a new version. The version history is a useful tool to trace the changes made in a knowledge base.

8. Applying Software Development Best Practices-Code Extensibility using GIT: GIT is a distributed revision controlled source code management tool”. For a large distributed project like an enterprise healthcare IT system, there can be multiple implementations supporting different information systems. There is a need for managing the development code for these information systems. The GIT repository is a popular approach to manage the source code of large distributed projects. It has the following features:

- a. When there is a need to extend the functionality of existing projects, the main software or the stable version is maintained and functionality is extended by using methods such as forking. GIT enables maintaining the stable state and allows extending of this software by managing the extended projects.
- b. In large distributed projects for an enterprise wide implementation, the functionality may need to be modified on a regular basis. GIT repository

maintains the versioning of these implementations. Thus allowing traceability across the implementation for modification of code.

Using the above capabilities of GIT repository for code management and versioning, the clinical knowledge bases such as clinical guidelines can be managed in a similar manner. Some complex clinical guidelines (master guidelines) have functionality that can be extended to other simpler guidelines. Thus the state of the master guideline can be maintained alongside reusing some common functionality in other guidelines.

Since the medical knowledge domain is susceptible to frequent changes, the knowledge of the clinical guidelines embedded in the knowledge bases can be maintained using the versioning mechanism of GIT. The knowledge base can be stored in online repositories such as GitHub, hence promoting sharable clinical knowledge.

- 9. Generalization of Approach:** The architectural approach for this integration solution is based on enabling loose coupling of multiple components that together achieve the business goals. Apart from healthcare this approach can be used in other business domains. The rule based decision support system can have a number of applications in businesses like insurance companies, real estate, weather forecasting, warning systems etc. An implementation based of SOA will help align the business goals with the technological implementation strategies of organizations.

7.3 Limitations

This research was conducted to provide a prototype model to test the feasibility of using a SOA based architecture for CDS. The following limitations are identified:

1. Implementing a real time healthcare setting using live physician requests and response from the CDS Framework would provide robust validation.
2. This work was implemented using a single x64 Server with instances of the components installed on virtual machines. If the hardware resources are improved, it would provide enhanced results by testing for a large number of requests and responses. In order to improve the CDS service results, the implementation solution was tested using Google Compute Engine cloud environment, which substantially improved the results as reflected in Chapter 5's results.

7.4 Future Work

7.4.1 Extending the CDS Framework for Complex guidelines

The thesis has provided results of clinical decision support in terms of diagnostic capabilities. The future work focuses on implementing guidelines that focus on longitudinal care i.e. treatment and follow-up processes. Secondly, since the SCA Composites can be reused, the knowledge contained in these implementations can be extended to more complex guidelines.

7.4.2 Extending the CDS Framework for Adaptive Case Management

The capabilities of CDS Framework are to be extended for adaptive case handling (unpredictable processes). In healthcare unpredictable process examples are disaster management and epidemic control strategies. The CDS process must adapt to unpredictable events, and allow addition of these changing conditions as processes at runtime in use by the physician or end user. By employing the technique of Case Based Reasoning as opposed to rule-based reasoning, this aim can be achieved.

7.4.3 SOA Governance

For a large scale enterprise implementation, the problem of SOA governance arises when there is a lack of mechanisms for managing a large number of services. For example in a large hospital, or trust (having two or three healthcare service organizations), there are different vendors providing services for separate information systems, like PAS, LIS A&E. The services provided by these vendors must be available in a registry including the metadata for them. The other systems must be able to discover these services and reuse them to fulfil their requirements. Another aspect of this reuse is that if there is a change made in the services which are utilized by other services, there must be a mechanism to notify the other systems. Additionally, if there is an error reported in the use of these services, the errors and their solutions must be communicated among the developing and testing teams. These capabilities are addressed by using a SOA Repository Artifact Model and Protocol (S-RAMP). For the CDS Framework, the SOA Governance architecture model is shown in Figure 39.

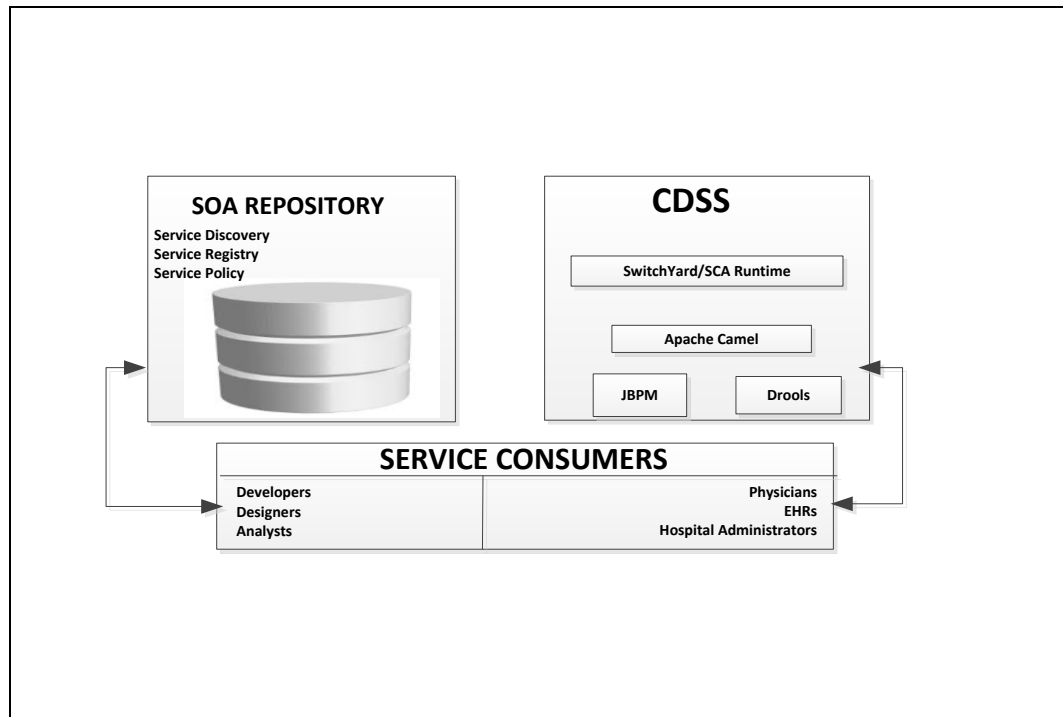


Figure 39 High level architecture for SOA Governance using S-RAMP

7.4.4 Introducing Terminology Service

To address semantic interoperability, the future work involves introducing a connection with the terminology server. This involves adding a terminology server component like National Library of Medicine's Unified Medical Language System and HL7 Common Terminology Services, to the CDS Framework, to handle the terminologies utilized by various EHRs.

7.5 Contributions

This thesis has contributed in the CDS area of Healthcare IT in various ways:

1. **Standards based Implementation:** The CDS Framework has leveraged HL7/OMG standards for implementation of healthcare IT services. The results of this research can guide future research in the area of implementing interface and data transmission standards.

2. **Open Source Implementation:** Use of Open source software promotes a culture of innovation and a sense of involvement for the developers in an organization. In various open source initiatives, the code is verified by multiple developers and enriched until it reaches a mature stage.
3. **Best practice implementation of SOA based Architecture:** Service Component Architecture has been viewed as a future trend in business IT applications. The SCA Composites are portable and can be reused in other applications.
4. **Addressing Challenges for CDS Implementation:** As indicated in Chapter 2, one of the grand challenges put forward by Sittig [25] was “*Create an architecture for sharing executable CDS modules and services*”. This research has demonstrated a feasible integration solution to address this challenge by enabling web-service based CDS at the point of care. By using the integration platform like enterprise service bus, various components work in a collaborative manner to provide the desired outcome.
5. **Application of BPM in healthcare:** This research has provided a practical implementation of BPM in healthcare domain. Clinical and administrative processes are viewed as business processes and are modelled using graphical notations such as BPMN. Although BPM is a vast research field in management, there is extensive research in progress about mechanisms of applying this research discipline in the healthcare field.
6. **Process/Social Interoperability:** As explained in Chapter 2, process interoperability is one of the critical success factors for an overall IT implementation in a healthcare setting. This type of interoperability optimizes workflows. To enable workflow guided clinical care, all the resources must work in coordination to provide timely services.
7. **Deployment Approaches:** The CDS Framework is an integration solution involving various components to facilitate CS functionality in a healthcare environment. The CDS framework has been tested for feasibility for on premises deployment as well as in a cloud environment. The deployment of the CDS service in the cloud has demonstrated an improvement in response time. Thus it can be said that availability of healthcare functionality such as CDS can provide improved outcomes by considering the cloud based deployment option.

7.6 Concluding Remarks:

Healthcare IT research will continue to evolve in the coming years. Because of availability of high speed internet, mobile platforms and cloud infrastructure, several prospects will motivate the improvement of healthcare functionality like computerized clinical decision support. To pursue innovation, it is important to embrace an unparalleled value system for the healthcare organization, which incorporates managing change, supportive leadership, healthcare professionals involvement and governance mechanism to ensure that technological intervention aligns with the organizational success goals. Recognizing success with innovative interventions like point-in time CDS, it is concluded that the use of standards based, open source technologies contributes towards the healthcare organization's goals. Additionally, this architecture can serve as a steady foundation in any industrial domain requiring rapid response to evolving business processes.

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APPENDIX A

LoadUI Test Results for CDS Framework

1. Evaluation Results for COPD Guideline:

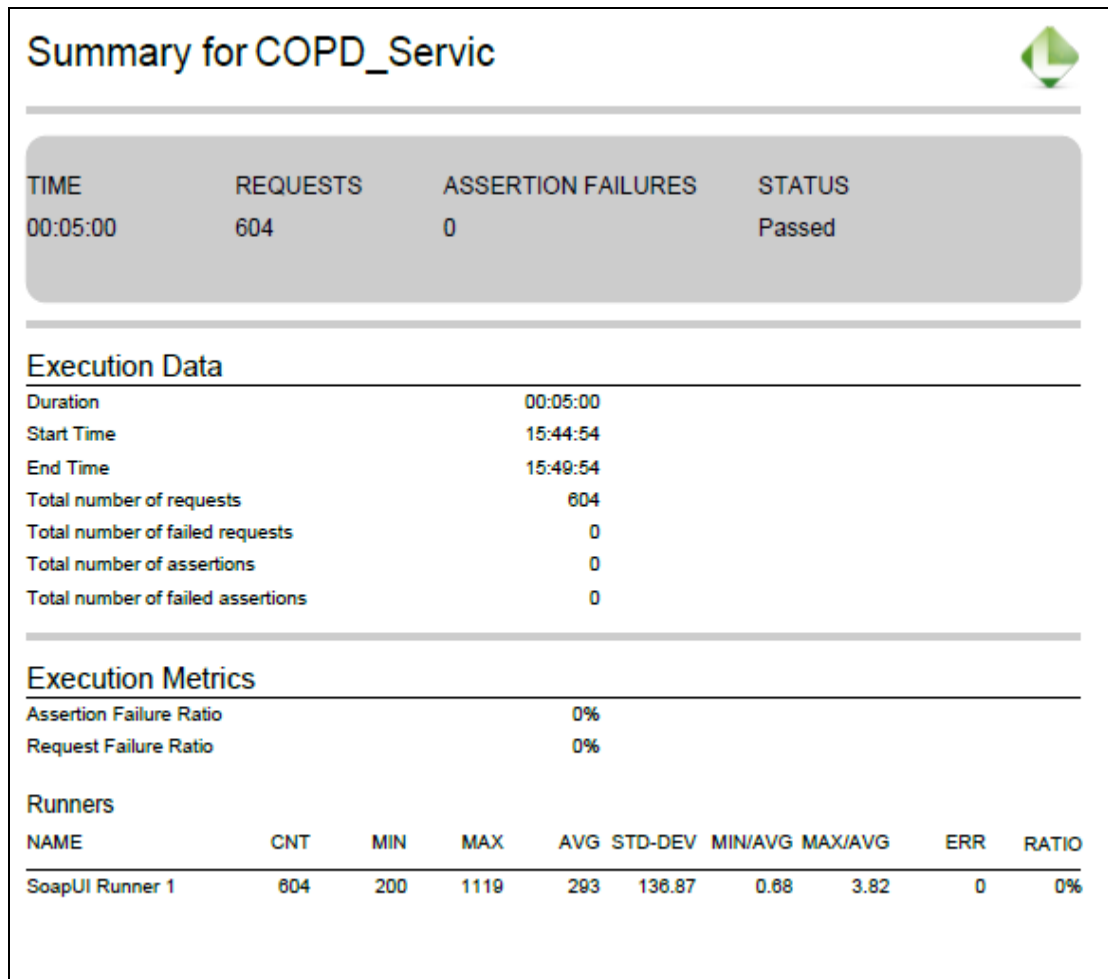


Figure 40 LoadUI Results for 20 Users

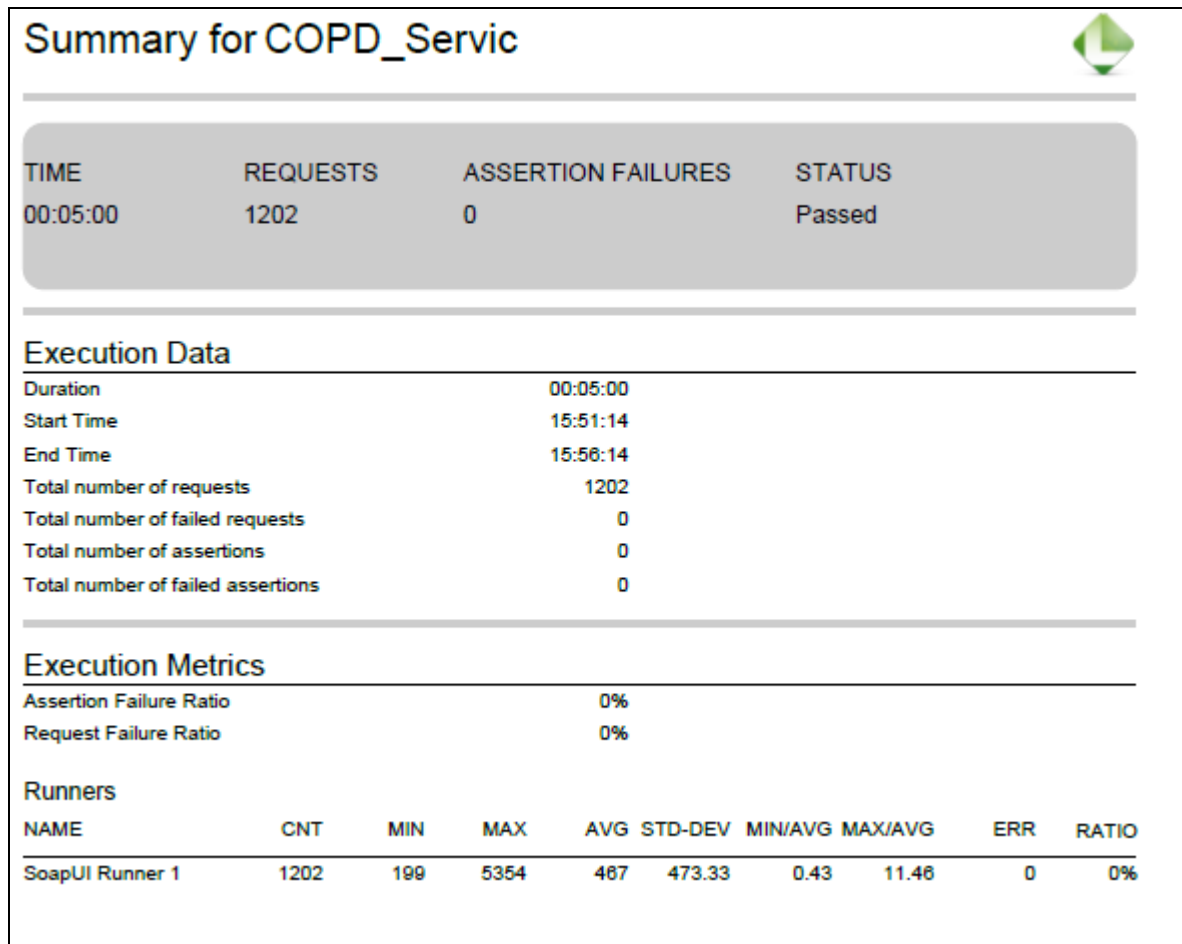


Figure 41 LoadUI Results For 40 Users

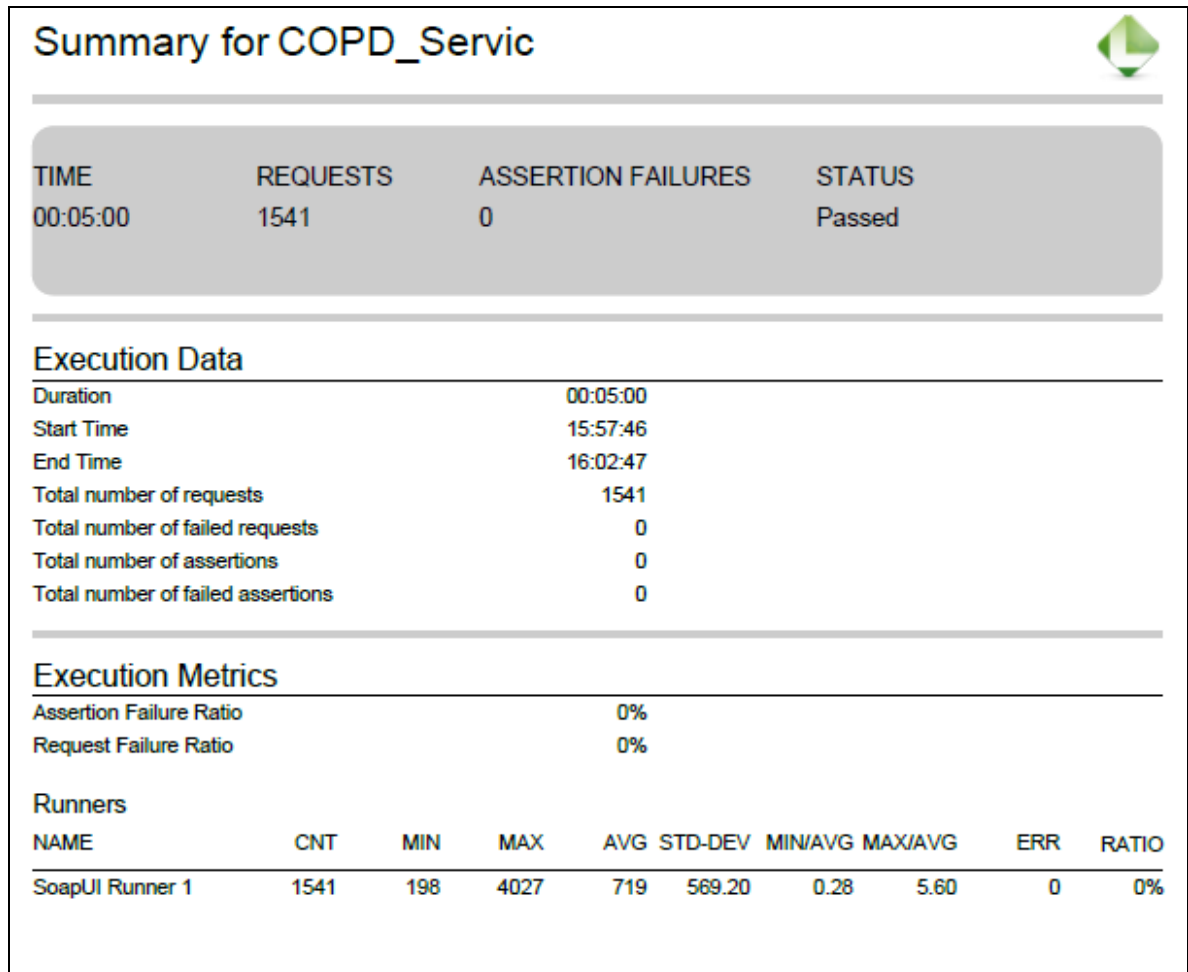


Figure 42 LoadUI Results For 50 Users

2. Evaluation Results for Lung Cancer Guideline

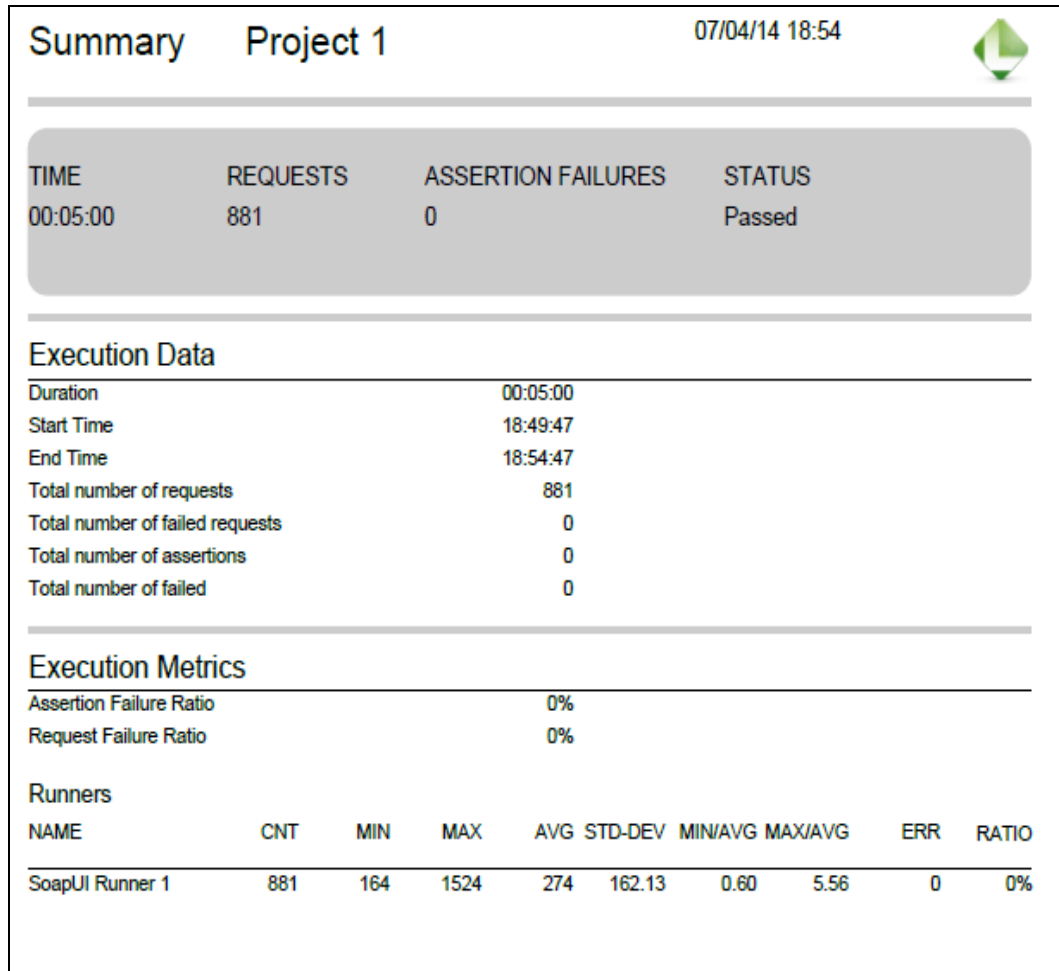


Figure 43 LoadUI Results for 30 Users

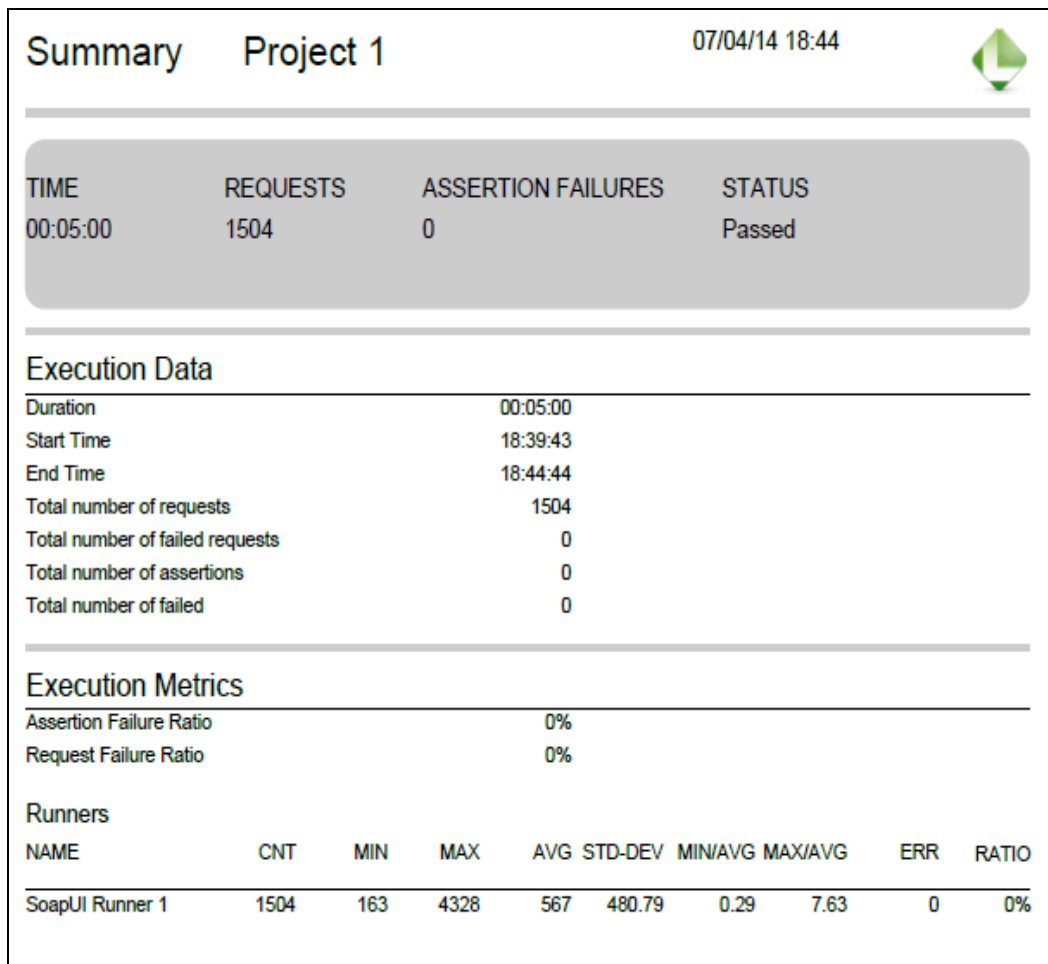



Figure 44 LoadUI Results for 50 Users

Summary

Project 1

07/04/14 19:07



TIME	REQUESTS	ASSERTION FAILURES	STATUS
00:05:00	1779	0	Passed

Execution Data

Duration	00:05:00
Start Time	19:02:11
End Time	19:07:12
Total number of requests	1779
Total number of failed requests	0
Total number of assertions	0
Total number of failed	0

Execution Metrics

Assertion Failure Ratio	0%
Request Failure Ratio	0%

Runners

NAME	CNT	MIN	MAX	AVG	STD-DEV	MIN/AVG	MAX/AVG	ERR	RATIO
SoapUI Runner 1	1779	162	7290	987	883.37	0.16	7.39	0	0%

Figure 45 LoadUI Results for 60 Users

3. Evaluation Results for Genetic Testing for Cystic Fibrosis

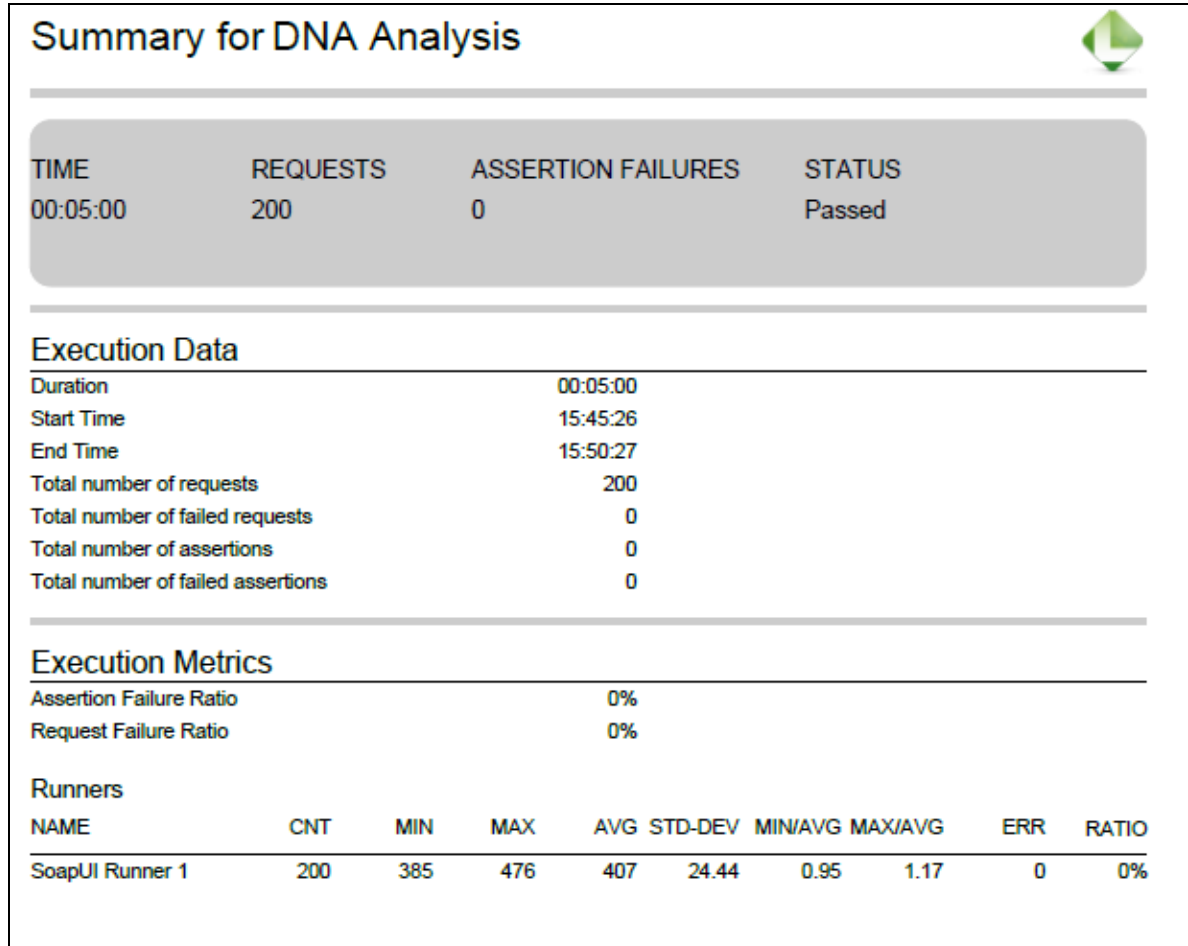


Figure 46 LoadUI Results for 20 Users

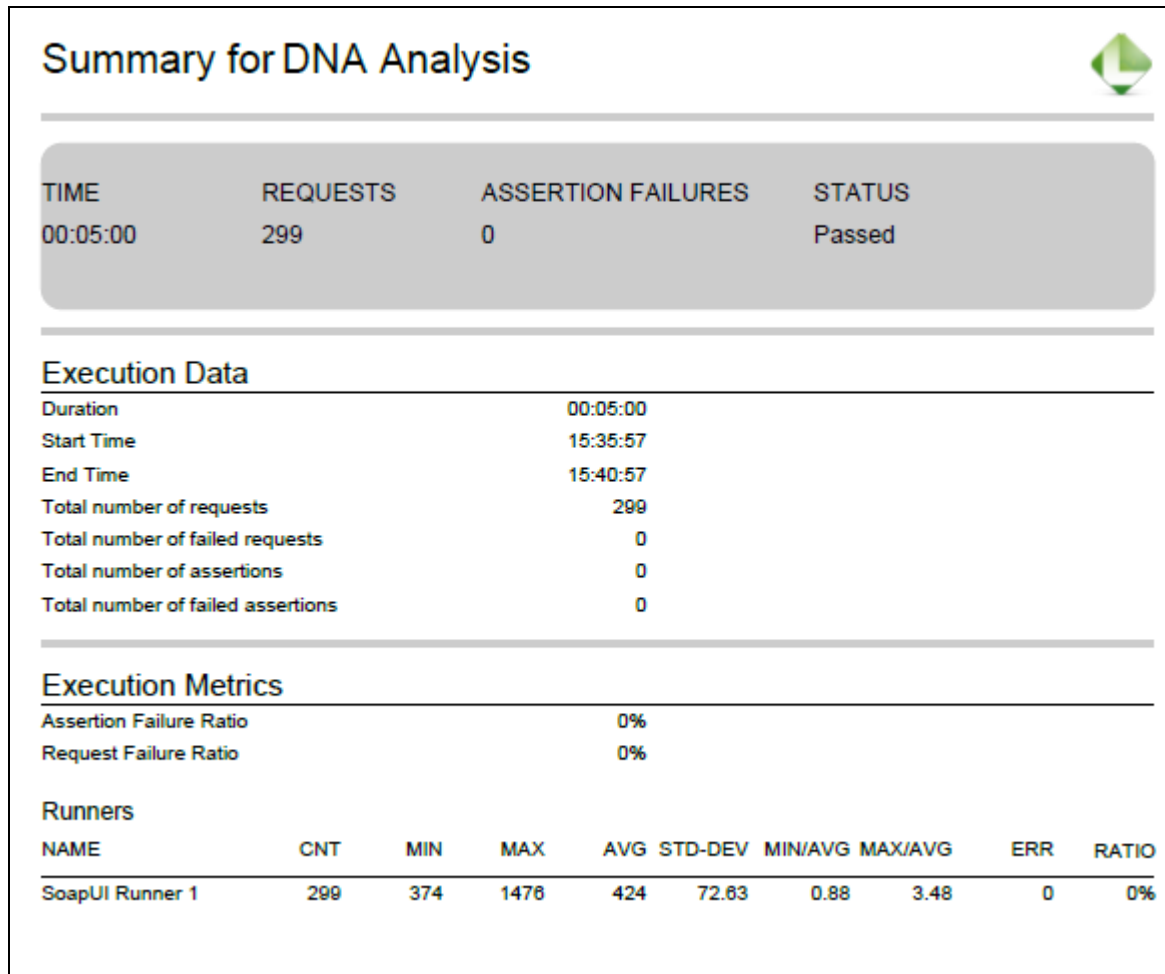


Figure 47 LoadUI Results for 30 Users

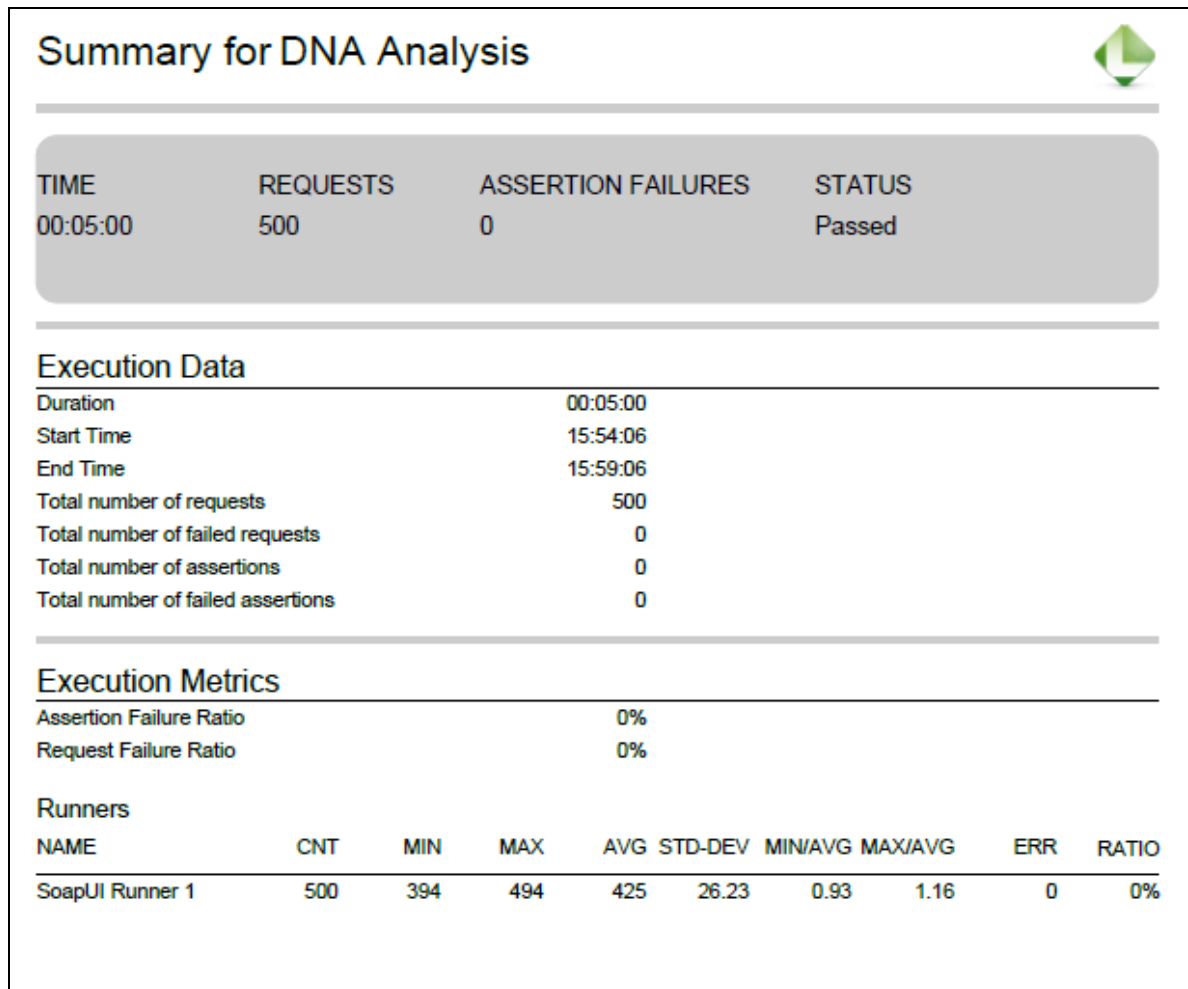


Figure 48 LoadUI Results for 50 Users

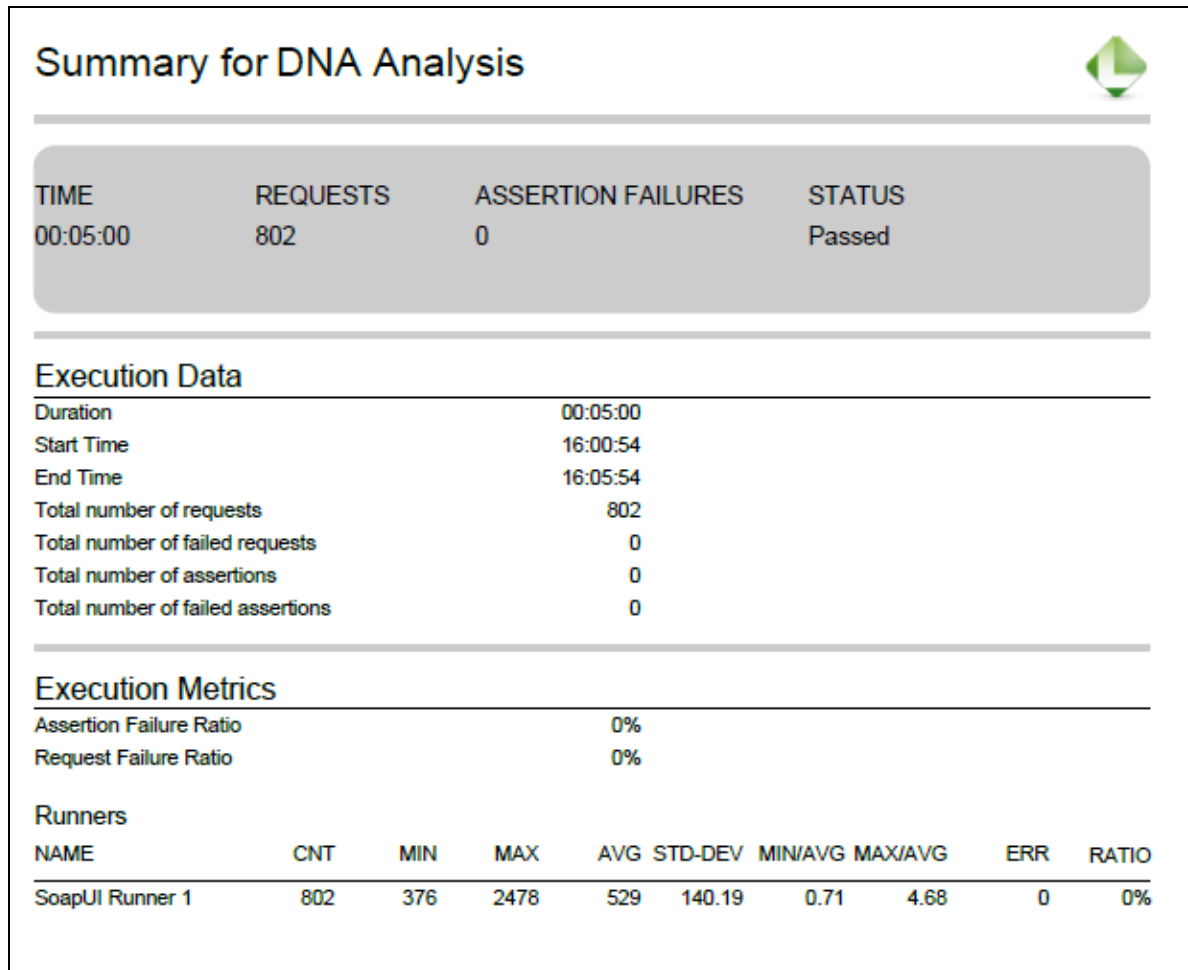


Figure 49 LoadUI Results for 80 Users

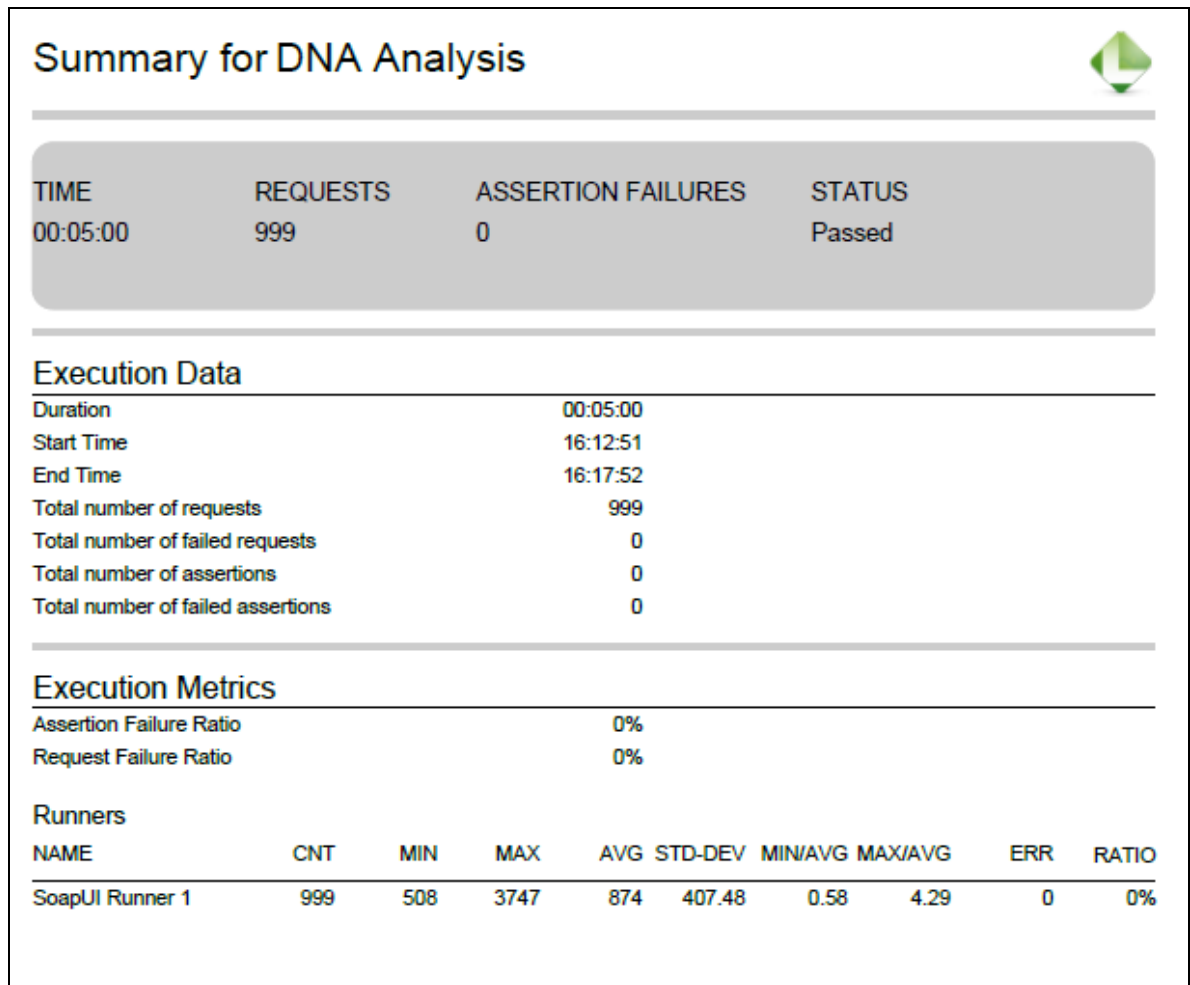





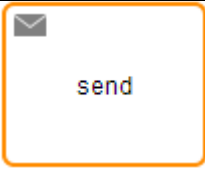
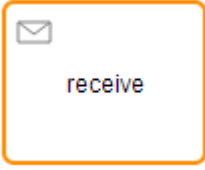
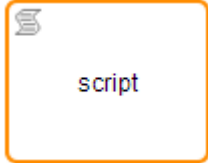

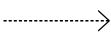



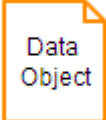

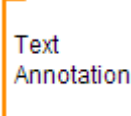
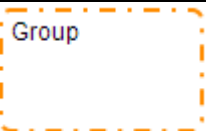


Figure 50 LoadUI Results for 100 Users

APPENDIX B

BPMN Modelling notation

Construct	Description	Symbol
Gateways		
Exclusive	Evaluates the state of the business process and based on the condition, breaks into two or more paths	
Parallel	Parallel gateways are used to represent two concurrent tasks in a business flow. It is also called "AND gateway"	
Event-Based Gateway	This gateway does routes based on which event takes place next	
Task		
Service Task	Service tasks are done by software. These are process functions applied as the process executes.	
User Task	Assigned by the process engine, these tasks are executed by people	
Send Task	These technical tasks are mainly used for calling web services asynchronously through message queues	
Receive Task	These are message receiving tasks.	

Script Task	Script Tasks execute in the process engine.	
Flows		
Sequence Flow	Sequence flows always have a source and a target	
Association	Association is a line between data object and an element	
Events		
Start Event	Represents start of a business process	
End Event	Represents termination of a business process	
Participants		
Lane	Pool represents a process into an organization. Lanes are used to represent roles in a process scope.	
Data Objects and Artifacts		
Data Object	Represents information flowing through a process like messages, emails	
Data Store	It is a place where a process can read or write data e.g, database or file.	
Text Annotation	Useful test to provide an insight to the execution of a task.	
Group	A group is a grouping of graphical elements that are within the same category. This does not affect the execution of tasks .	

Source: Business Process Model and Notation Specification version 2.0 , Object Management Group, Available from: <http://www.bpmn.org/> and <http://www.omg.org/spec/BPMN/2.0/>